EXHIBIT C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. WALMART INC. AND WAL-MART STORES EAST, LP, Defendants.	Jury Trial Demanded Case No. _____

COMPLAINT

TABLE OF CONTENTS

The United States of America files this Complaint against Walmart Inc. and Wal-Mart Stores East, LP (collectively "Walmart"), and alleges as follows:

INTRODUCTION

1. The United States of America brings this civil enforcement action against Walmart for violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "CSA"), 21 U.S.C. §§ 801 *et seq*.

2. The CSA comprehensively regulates every participant in the supply chain for controlled substances, from manufacturers to wholesale distributors to retail pharmacies. Because controlled substances by definition are drugs with the potential for abuse, this comprehensive scheme is designed to prevent the "diversion"—*i.e.*, the illegal misuse—of controlled substances, including prescription opioids. Under the CSA, every participant in the supply chain bears responsibility for preventing the misuse of controlled substances.

3. Walmart operates more than 5,000 pharmacies nationwide that dispense prescription opioids and other controlled substances. In addition, until 2018, Walmart acted as a wholesale distributor of controlled substances for its own pharmacies.

4. As both a pharmacy and a distributor, Walmart assumed critical gatekeeping responsibilities under the CSA. At two stages—when deciding whether to fill its pharmacies' wholesale orders for controlled substances from its distribution warehouse, and when deciding whether to fill individuals' prescriptions for controlled substances—Walmart was required by the CSA to take steps to prevent the diversion of the prescription drugs it sold.

5. As a nationwide dispenser *and* distributor of opioids, and given the sheer number of pharmacies it operates, Walmart was uniquely well positioned to prevent the illegal diversion of opioids. Yet, for years, as the prescription drug abuse epidemic ravaged the country, Walmart

abdicated those responsibilities.

6. First, as a pharmacy, Walmart knowingly violated well established rules requiring it to scrutinize controlled-substance prescriptions to ensure that they were valid—that is, issued by prescribers in a legitimate manner for legitimate purposes, not for purposes of abuse or other diversion. These rules required Walmart to recognize, investigate, and resolve signs of a prescription's invalidity—"red flags," in pharmacy terminology—prior to filling a controlled-substance prescription. Walmart was well aware of these rules, but made little effort to ensure that it complied with them. In fact, Walmart made it difficult for its pharmacists to follow the rules. Walmart managers put enormous pressure on pharmacists to fill prescriptions—requiring pharmacists to process a high volume of prescriptions as fast as possible, while at the same time denying them the authority to categorically refuse to fill prescriptions issued by prescribers the pharmacists knew were continually issuing invalid prescriptions. And while Walmart's compliance unit collected voluminous information indicating that Walmart was routinely being asked to fill invalid controlled-substance prescriptions, that unit for years withheld that information from pharmacists and allowed them to continue dispensing opioids based on invalid prescriptions.

7. As a result of Walmart's failures to take seriously its gatekeeping duties as a pharmacy, Walmart—during the prescription drug abuse epidemic—unlawfully filled thousands upon thousands of invalid controlled-substance prescriptions.

a. Walmart filled prescriptions issued by prescribers who Walmart pharmacists had repeatedly reported were acting as egregious "pill mills"—even when Walmart was alerted that other pharmacies were not filling prescriptions for those prescribers. In fact, some of those pill-mill prescribers specifically told their patients to

fill their prescriptions at Walmart.

b. Walmart also filled prescriptions with glaringly obvious red flags, such as prescriptions for "trinities" and other well-known and highly dangerous drug "cocktails" that Walmart pharmacists knew were predominantly sought by individuals engaging in drug abuse.

c. And Walmart filled prescriptions that were the same or similar to other prescriptions it had previously recognized as invalid for the same customer—which meant that when a Walmart pharmacist recognized that a customer's prescription was invalid, the customer could simply shop around for another Walmart pharmacist or store to fill the same or a similar prescription.

8. Second, as a wholesale distributor, Walmart had a basic obligation to detect suspicious orders placed by its own pharmacies for controlled substances, and to report those orders to the Drug Enforcement Administration ("DEA"). Walmart knew that this rule was designed to prevent diversion of controlled substances and that it would face civil penalties and other potential enforcement if it failed to comply. And compliance could have been readily accomplished, as Walmart had not only adequate resources but also a wealth of information about its pharmacies. But for years, Walmart kept in place a system that it knew was failing to adequately detect and report suspicious orders. Walmart periodically considered fixing its system, but time and time again it chose not to spend the time, money, and effort needed to bring its process into compliance.

9. Because Walmart shirked this key legal obligation as a distributor, Walmart failed to detect and report at least hundreds of thousands of suspicious orders. This failure enabled Walmart's pharmacies to place and receive controlled-substance orders that went essentially

unmonitored, even when those orders were suspicious and could have revealed that diversion was ongoing.

10. Predictably, Walmart's violations of the CSA as both a pharmacy and a distributor had disastrous results, harming individuals who filled their controlled-substance prescriptions at Walmart and then abused the drugs. And given the nationwide scale of those violations, Walmart's failures to follow basic legal rules helped fuel a national crisis.

11. Accordingly, the United States seeks civil penalties under the CSA and appropriate injunctive relief.

A. As a pharmacy, Walmart violated the rules for dispensing controlled substances.

12. Walmart is one of the country's largest pharmacy chains. It operates more than 5,000 pharmacies at Walmart-branded and Sam's Club-branded retail stores nationwide. Through its pharmacies, Walmart dispenses controlled substances to individuals.

13. As the final step in the supply chain before individuals receive controlled substances, pharmacies are the last line of defense in preventing abuse and misuse of controlled substances. The CSA and its implementing regulations therefore require pharmacies to comply with certain legal requirements before filling controlled-substance prescriptions.

14. Specifically, under the CSA, pharmacies may dispense controlled substances only pursuant to a valid prescription. A prescription must satisfy two requirements to be valid—or, in CSA terminology, "effective." It must be issued (1) for a legitimate medical purpose and (2) by a medical practitioner acting in the usual course of his or her professional practice. *See* 21 C.F.R. § 1306.04(a).

15. Additionally, in filling prescriptions for controlled substances, pharmacists are required to adhere to the usual course of professional pharmacy practice. *See id.* § 1306.06.

When presented with a controlled-substance prescription, the pharmacist, in order to act in the usual course of professional practice, must identify and resolve any "red flags"—signs indicating the invalidity of the prescription—before filling the prescription.

16. Walmart knew from its own past experience that if its pharmacists failed to comply with their legal obligations when dispensing controlled substances, Walmart could face enforcement action. As discussed below in Part II.A.2.b, DEA initiated an administrative proceeding in 2009 seeking to revoke Walmart's registration for a pharmacy that DEA alleged had failed to comply with its legal obligations when filling controlled-substance prescriptions.

17. To resolve that proceeding, Walmart entered into an agreement with DEA in 2011 in which Walmart agreed to adopt a national compliance program intended to ensure that it fulfilled its legal obligations when filling controlled-substance prescriptions. Walmart also agreed to collect reports from its pharmacists when those pharmacists determined that controlled-substance prescriptions were invalid and refused to fill them.

18. The many refusal-to-fill reports that Walmart collected were shocking. They revealed, over and over again, that all across the country, Walmart pharmacies were regularly being presented with invalid prescriptions. For example, Walmart pharmacists alerted Walmart's compliance unit to numerous prescribers who were "known pill mills," did "not practice real medicine," had "horrendous prescribing practices," and continually issued high-dose controlled-substance prescriptions for many individuals. In addition, the reports showed that Walmart pharmacists were repeatedly being presented with other prescriptions showing such obvious red flags on their face that Walmart pharmacists recognized the prescriptions as invalid.

19. While Walmart's compliance unit collected and compiled all this information about invalid prescriptions, it chose, for years, *not* to alert Walmart pharmacists so that they

could use that information to determine whether to fill similar prescriptions. As a director in the compliance unit, B.N., acknowledged in an email, rather than analyzing the refusal-to-fill reports, the compliance unit viewed "[d]riving sales and patient awareness" as "a far better use of our Market Directors and Market Manager's time."

20. At the same time, Walmart's managers made it exceedingly difficult for its pharmacists to comply with their legal obligations, by pressuring them to fill prescriptions as quickly as possible. Managers told pharmacists that prescriptions had to be filled quickly because "shorter wait times keep patients in store." They urged pharmacists to speed up the time it took to fill each prescription because filling prescriptions "is a battle of seconds" and "[w]ait times are our Achilles heel!" Pharmacists, in turn, complained to Walmart's compliance unit that the high volume of prescriptions, combined with Walmart's low staffing, "doesn't allow time for individual evaluation of prescriptions."

21. Walmart's approach led it to fill thousands upon thousands of controlled-substance prescriptions that Walmart knew, in multiple ways, were highly likely to be invalid.

22. First, as discussed below in Part II.B, Walmart filled prescriptions that it knew were issued by "pill-mill" prescribers. Walmart's compliance unit had compiled extensive evidence that these particular prescribers were writing prescriptions that were invalid—outside the usual course of professional practice, without a legitimate medical purpose, or both. Pharmacists reported that some prescribers told their patients to fill prescriptions at Walmart. For example, one pharmacist reported learning that a prescriber "tells his patients that only Wal-Mart will fill his prescriptions." Pharmacists made the urgency of their reports clear. For example, one pharmacist reported that he had "too much invested in [his] career and family to continue to risk" filling prescriptions for a pill-mill prescriber. But the compliance unit

knowingly withheld this information from Walmart pharmacists, even though it was apparent that Walmart pharmacists would be presented with many more prescriptions from these same problem prescribers. And, sure enough, for years, despite these unresolved red flags, Walmart continued to fill many more prescriptions issued by these known pill-mill prescribers.

23. Second, as discussed below in Part II.C, Walmart filled numerous prescriptions that, on their face, showed such obvious red flags—such as highly dangerous, commonly abused "cocktails" of drugs, sometimes in alarmingly high quantities—that Walmart pharmacists would have known that the prescriptions had a very high probability of being invalid.

24. Third, as discussed below in Part II.D, Walmart filled many prescriptions that pharmacists knew were invalid because the prescriptions presented the same or similar red flags as the same or similar prescriptions other Walmart pharmacists had previously recognized as invalid for the same patient.

25. In all, from June 26, 2013, to the present (hereinafter referred to as the "Dispensing Violations Period"), Walmart filled thousands upon thousands of invalid prescriptions and, in doing so, repeatedly violated the CSA dispensing requirements identified in 21 C.F.R. § 1306.04(a) and § 1306.06. Walmart filled prescriptions that it knew were not issued for a legitimate medical purpose, or were not issued by a medical practitioner acting in the usual course of his or her professional practice, or both, in violation of section 1306.04(a). And by filling those prescriptions despite the red flags, Walmart pharmacists failed to adhere to the usual course of professional pharmacy practice, in violation of section 1306.06.

26. Walmart violated the CSA each time it violated 21 C.F.R. § 1306.04(a) or § 1306.06 in dispensing a controlled substance. *See* 21 U.S.C. § 842(a)(1). For each violation,

Walmart is liable for a civil penalty. *See* 21 U.S.C. § 842(c)(1). The Court also may grant injunctive relief to address and restrain these violations. *See* 21 U.S.C. § 843(f).

B. As a distributor, Walmart violated its duty to detect and report suspicious orders of controlled substances.

27. As relevant to this Complaint, Walmart also operated as a distributor of controlled substances between June 26, 2013, and November 29, 2017 (hereinafter referred to as the "Distribution Violations Period"). In this role, Walmart shipped controlled substances to its own pharmacies around the country.

28. Distributors of controlled substances are required by the CSA to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and "shall inform" DEA of those suspicious orders "when discovered." *See* 21 C.F.R. § 1301.74(b). Thus, a distributor must itself detect and identify suspicious orders and report them to DEA. This requirement protects against diversion and abuse by requiring distributors to monitor pharmacies for warning signs of such misconduct.

29. The regulation provides that suspicious orders "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id*. In other words, orders that are unusual in one or more of those three ways—size, pattern, or frequency—are deemed "suspicious orders," and a distributor must detect and report them. The regulation does not limit "suspicious orders" to those three categories, however. It states, non-exclusively, that suspicious orders "include" those categories.

30. As discussed below in Part III.A, because Walmart acted as its own distributor for controlled substances, it had a special advantage: Walmart had access to extensive data and other information that gave it the ability—had it wanted to—to investigate the circumstances underlying orders for controlled substances.

31. Nevertheless, as discussed below in Part III.B, for years Walmart maintained a wholly inadequate system for detecting and reporting suspicious controlled-substance orders placed by its pharmacies. Because Walmart's suspicious-order monitoring system suffered from numerous flaws, Walmart routinely failed to detect and report orders that exhibited unusual frequency, deviated from the normal ordering pattern, or were of unusual size. Although Walmart knew its flawed system did not comply with the CSA, for years Walmart failed to use its ample resources to remedy these deficiencies.

32. Walmart's compliance unit knew that Walmart could face penalties for not complying with its obligation to detect and report suspicious orders. For example, in 2014, Walmart considered modifying Walmart's system to "avoid DEA enforcement as a result of non-compliance with 21 CFR 1301.74(b)."

33. But rather than bringing its system into compliance with its legal obligations to detect and report all suspicious orders, Walmart again prioritized speed. Members of Walmart's compliance unit complained that its system for receiving and shipping orders was so fast that it allowed only "limited time for evaluation" of each order, that there were "too many orders to review each line [of alerts] in detail," and that Walmart's system "did not allow alerted orders to be 'held' pending evaluation."

34. Because Walmart prioritized speed, it failed to detect and report most of the suspicious orders that it received from its pharmacies. As discussed below in Part III.C, due to Walmart's defective systems, Walmart failed to detect and report at least hundreds of thousands of suspicious orders of controlled substances during the Distribution Violations Period. Over an approximately four-year period, a time during which Walmart shipped an estimated 37.5 million controlled-substance orders to its pharmacies, it reported only 204 suspicious orders to DEA—in

other words, almost none. By comparison, during the same time period, Walmart's back-up distributor, McKesson Corporation, which filled orders only when Walmart could not and which therefore shipped far fewer than 37.5 million orders, reported to DEA more than 13,000 suspicious orders from Walmart pharmacies.

35. Walmart's grossly inadequate suspicious-order monitoring program contributed to its failure to stop diversion of controlled substances at its pharmacies, as discussed below in Part III.D. Walmart's systematic, years-long failure to detect and report each of its suspicious orders created a major obstacle to efforts to combat the prescription drug abuse epidemic. Had the company identified and investigated its hundreds of thousands of suspicious orders, it could have stopped the pharmacies that were placing those orders from unlawfully filling controlled-substance prescriptions or otherwise contributing to the diversion of controlled substances.

36. Even when Walmart did detect a suspicious order, it often already had shipped the order and did not have it shipped back. As a Senior Manager for Logistics observed in an email, "if we see an issue that suggests the product shouldn't have shipped, we just leave it at the store and let it enter the market," even though having the order shipped back "feels like the more socially responsible approach…."

37. Each time Walmart failed to comply with its legal obligation to detect and report a suspicious order, it violated the CSA. Pursuant to 21 U.S.C. § 842(a)(5), it is unlawful for a distributor to refuse or negligently fail to make or furnish reports, notifications, or information that are required under the CSA. For each violation of 21 U.S.C. § 842(a)(5), Walmart is liable for a civil penalty. *See* 21 U.S.C. § 842(c)(1)(A), (B).

C. Walmart systematically violated the CSA even as it recognized the prescription drug abuse epidemic gripping the nation.

38. During the very period when Walmart was systematically failing to comply with

its legal responsibilities to protect against the diversion of prescription drugs, the prescription drug abuse epidemic in the United States was exploding.

39. Between 1999 and 2018, more than 232,000 people died in the United States from overdoses involving prescription opioids. https://www.cdc.gov/drugoverdose/data/prescribing/overview.html (last visited October 26, 2020). Such deaths "were more than four times higher in 2018 than in 1999." *Id.*

40. In 2016 alone, opioid overdoses caused more than 42,000 deaths—more than any previous year on record. U.S. Department of Health and Human Services, *About the Epidemic*, https://www.hhs.gov/opioids/about-the-epidemic (last visited October 26, 2020). An estimated 40 percent of those deaths—more than 16,800—involved prescription opioids. *Id.*

41. Indeed, there were so many opioid-related deaths in 2015 and 2016 that the epidemic caused U.S. life expectancy to decrease in both years. *CDC in Action: 2018 Response to the Opioid Crisis*, https://www.cdc.gov/opioids/pdf/Overdose-Snapshot-2018_Final_508.pdf (last visited Dec. 15, 2020). This was the first two-year decrease in life expectancy in over half a century. *See* National Vital Statistics Reports, Vol. 68, No. 7, June 24, 2019, at Table 19, *https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_07-508.pdf* (last visited Nov. 17, 2020).

42. Walmart was well aware of the severity and scope of the prescription drug abuse epidemic. As early as October 2013, Walmart acknowledged that "drug overdose, (the majority being Rx [prescription] Meds), is now the number one cause of accidental deaths in the U.S."

43. Nevertheless, Walmart routinely ignored the very legal requirements that could have helped stem the epidemic. In doing so, Walmart endangered its customers and contributed to the prescription drug abuse epidemic that has claimed hundreds of thousands of lives.

44. Walmart's violations described above had grave consequences. Some individuals

who filled invalid prescriptions for controlled substances at Walmart died soon thereafter of overdoses related to those prescriptions.

PARTIES

45. Plaintiff is the United States of America.

46. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a multinational retail corporation incorporated in the State of Delaware.

47. Along with retail stores and other business units, Walmart Inc. operates one of the largest pharmacy chains in the United States, consisting of more than 5,000 DEA-registered pharmacies located in Walmart and Sam's Club retail stores in the United States and its territories. As a pharmacy chain, Walmart Inc. dispenses controlled substances through its agents and employees.

48. Until 2018, Walmart Inc. also acted as a distributor of controlled substances for its pharmacies around the country. From 2000 to approximately May 2018, Walmart Inc. operated at least six distribution centers that distributed controlled substances to its pharmacies in the United States. The distribution centers were located in Bentonville, Arkansas; Rogers, Arkansas; Tifton, Georgia; Crawfordsville, Indiana; Hanford, California; and Williamsport, Maryland. Collectively, Walmart self-distributed to its pharmacies tens of millions of shipments of controlled substances.

49. The DEA registrant for those distribution centers was Defendant Wal-Mart Stores East, LP. Wal-Mart Stores East, LP is also incorporated in Delaware.

50. At all times relevant to this action, Walmart Inc. was responsible for the compliance of the pharmacies and the distribution centers with all provisions of the CSA and the regulations promulgated under the CSA.

51. For ease of reference, Defendants Walmart Inc. and Wal-Mart Stores East, LP are generally referred to herein as "Walmart" except where identification of the particular entity is significant. In addition, where it is useful to identify the business segment or refer to a brand (such as "Walmart-branded stores" or "Sam's Club-branded stores"), the distinction between those business segments or brands is drawn.

JURISDICTION AND VENUE

52. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1345, and 1355(a), and 21 U.S.C. § 842(c)(1) and § 843(f)(2).

53. This Court has personal jurisdiction over both Defendants because both are incorporated in Delaware.

54. Venue is proper in this district under 28 U.S.C. § 1395(a) and 21 U.S.C. § 843(f) because both Defendants can be found and reside in this district.

I. WALMART'S CSA OBLIGATIONS AS A PHARMACY AND A DISTRIBUTOR.

A. Controlled substances generally.

55. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for abuse. Controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use to treat patients, their abuse potential, and the likelihood they will cause dependence if abused. A drug becomes a "controlled substance" when it is added to one of these schedules.

56. Schedule I drugs are those deemed not to have an accepted medical use. The remaining schedules—Schedules II through V—are relevant to this case. The drugs in these schedules have legitimate medical purposes and, in the case of Schedules II through IV, require a

prescription. *See* 21 U.S.C. § 829.

57. Schedule II lists controlled substances that have "a high potential for abuse"; that, if abused, "may lead to severe psychological or physical dependence"; but that nonetheless have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *See* 21 U.S.C. § 812(b)(2). Schedule II includes opioid-based painkillers such as oxycodone, hydrocodone, and methadone, and stimulants such as amphetamine. *See* 21 C.F.R. § 1308.12.

58. Schedule III lists controlled substances that have "a potential for abuse less than the drugs or other substances in schedules I and II"; that, if abused, "may lead to moderate or low physical dependence or high psychological dependence"; but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(3). Schedule III includes buprenorphine, a medication approved to treat opioid use disorder. *See* 21 C.F.R. § 1308.13.

59. Schedule IV lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule III"; that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III"; but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(4). Schedule IV includes alprazolam (commonly sold under the brand name Xanax), diazepam (commonly sold under the brand name Valium), and lorazepam (commonly sold under the brand name Ativan). *See* 21 C.F.R. § 1308.14. Each of these three drugs belongs to a class of medications called benzodiazepines, which act on the brain and nerves to produce a calming effect. Schedule IV also includes carisoprodol, a muscle relaxant that is often sold under the brand name Soma, and zolpidem, an insomnia medication

that is often sold under the brand name Ambien. As explained later, carisoprodol and zolpidem are components of dangerous drug "cocktails" sought by individuals known to abuse or misuse prescription drugs.

60. Schedule V lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule IV"; that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV"; but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(5). Schedule V includes certain dosages of promethazine-codeine. *See* 21 C.F.R. § 1308.15.

B. The CSA creates a closed system for regulating controlled substances.

61. Through the CSA, Congress sought to prevent diversion and abuse of controlled substances. To accomplish this goal, the CSA created a "closed" system for regulating and monitoring controlled substances, under which it is unlawful to distribute, dispense, or possess any controlled substance except in a manner authorized by law. The CSA and its implementing regulations govern every step in the handling of certain drugs, from their production in a manufacturing facility to their distribution from a warehouse, and from their prescription by a medical practitioner to their dispensing by a pharmacy filling a prescription.

62. The system is "closed" in that each part of the supply chain—including manufacturers, distributors, prescribers, and pharmacies—must register with DEA and comply with the CSA and its implementing regulations. *See* 21 U.S.C. §§ 822(a)(2) and 823(f).

63. Entities who register with DEA (known as "registrants") agree to comply with the CSA and its implementing regulations, and may manufacture, distribute, prescribe, or dispense controlled substances only to the extent authorized by their registration and the law. *See* 21

U.S.C. §§ 822(a)–(b), 823(f).

C. A pharmacy must comply with certain rules before it fills a controlled-substance prescription.

64. Ordinarily, the last step in the closed distribution system is the pharmacy that, after being presented with a prescription, dispenses a controlled substance to the end user.

65. As noted above, Walmart operated pharmacies that "dispensed" controlled substances. "Dispensing" generally means delivering a controlled substance to an end user pursuant to a physician's prescription. *See* 21 U.S.C. § 802(10); 21 C.F.R. §§ 1300.01, 1306.03(a).

66. The CSA designates pharmacies as "practitioners" that are permitted to handle controlled substances if they adhere to the course of "professional practice." The CSA defines the term "practitioner" to include a physician, pharmacy, or other person permitted by law to distribute or dispense a controlled substance "in the course of professional practice or research." *See* 21 U.S.C. § 802(21).

67. Pharmacies that wish to dispense controlled substances are required under the CSA to register with the Attorney General. *See* 21 U.S.C. § 823(f) ("The Attorney General shall register … pharmacies, as distinguished from pharmacists … to dispense … controlled substances…."). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

68. DEA reviews applications for registration (and renewals of registration) by pharmacies and, where necessary, pursues revocations of registrations. In deciding whether to issue or deny a registration for a pharmacy, DEA considers various factors, including whether the applicant for a registration has complied with the laws relating to controlled substances and its other conduct related to public health and safety. *See* 21 U.S.C. § 823(f).

69. Pharmacists who dispense controlled substance as an "agent or employee" of a pharmacy registered with DEA need not register individually with DEA. *See* 21 U.S.C. §§ 822(c)(1), 823(f).

70. In general, the CSA prohibits pharmacies from dispensing most controlled substances without a "prescription issued by a practitioner." *See* 21 U.S.C. § 829(a) ("no controlled substances in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner"), § 829(b) (requiring a prescription for dispensing controlled substances in Schedule III or IV).

71. The CSA makes it unlawful "for any person … to … dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1).

72. The Attorney General has promulgated, in 21 C.F.R. Part 1306 ("Prescriptions"), rules for when prescriptions may be filled pursuant to a prescription in accordance with 21 U.S.C. § 829. *See* 21 C.F.R. § 1306.01 ("Rules governing the issuance, filling, and filing of prescriptions pursuant to [21 U.S.C. § 829] are set forth generally in this section and specifically by the sections of this part.").

73. As relevant here, Part 1306 sets forth three rules pharmacies must follow when dispensing controlled substances. For each controlled-substance prescription, a pharmacist must (1) determine that the prescription was issued by a medical practitioner adhering to the usual course of his or her professional practice, (2) determine that the prescription is for a legitimate medical purpose, and (3) in filling the prescription, adhere to the usual course of his or her own professional pharmacy practice.

74. Walmart was required to adhere to these three requirements in its role as a

pharmacy dispensing controlled substances.

1. The pharmacist must determine whether the prescription was issued in the usual course of professional practice and for a legitimate medical purpose.

75. 21 C.F.R. § 1306.04(a) defines certain requirements for a controlled-substance prescription to be valid or "effective" and also imposes obligations on both the medical practitioner who issues the prescription and the person who fills the prescription.

76. To be valid or effective, a prescription for a controlled substance must meet two requirements. First, it must be issued by a medical practitioner acting in the usual course of his professional practice. *See* § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued … by an individual practitioner acting in the usual course of his professional practice…. An order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) ….").

77. Second, the prescription must be issued for a legitimate medical purpose. *See* § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose…"). For example, a prescription is not issued for a legitimate medical purpose if it is issued or sought for nonmedical use or abuse by a patient.

78. While section 1306.04(a) imposes a responsibility on prescribers (medical practitioners) to issue valid prescriptions, it also imposes a "corresponding responsibility" on the pharmacist who fills the prescription to independently determine that the prescription is valid—that is, was issued for a legitimate medical purpose, and in the usual course of professional practice. *See* § 1306.04(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."). The pharmacist's corresponding

responsibility includes, *inter alia*, identifying and attempting to resolve red flags; to document the resolution if the red flag is resolved; and to refuse to fill the prescription if the red flag is not resolved.

2. The pharmacist also must adhere to professional pharmacist practice standards, which require identifying and resolving any "red flags."

79. A third relevant rule that a pharmacist must follow in filling prescriptions for controlled substances is found in section 1306.06, which requires that the pharmacist's conduct must adhere to the usual course of his or her professional practice as a pharmacist. *See* 21 C.F.R. § 1306.06 (requiring that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice…."). This requirement follows the CSA's general approach that a practitioner is permitted to handle controlled substances when consistent with the "course of professional practice." *See* 21 U.S.C. § 802(21).

80. Pharmacists are professionals who must be licensed by the states in which they practice. A basic licensing requirement common across states is a Doctor of Pharmacy ("Pharm.D.") degree, which is granted upon successful completion of a doctoral-level program that typically requires three to four years of study. After successfully attaining a Pharm.D. degree, practicing pharmacists must pass two licensing exams.

81. Pharmacists are trained about the role they play in preventing prescription drug abuse and diversion. For example, the Accreditation Council for Pharmacy Education, which publishes accreditation standards and guidelines for Pharm.D. programs, requires that the Pharm. D. curriculum include a discussion of the laws regulating pharmacy practice and the mitigation of drug abuse and diversion.

82. In evaluating the validity of a controlled-substance prescription, pharmacists cannot rely exclusively on the fact that it was issued by a medical practitioner. Rather, to assess

a prescription's validity, a pharmacist must consider any signs that a prescription may be invalid or that the controlled substances may be abused or misused.

83. Pharmacists call these signs of invalidity "red flags." Red flags may arise based on the prescriber who issued the prescription (*e.g.*, where a prescriber issues many more prescriptions of opioids for higher quantities than do comparable prescribers), the prescription itself (*e.g.*, where the combination of drugs prescribed is frequently sought by individuals known to abuse or misuse prescription drugs for nonmedical purposes), or the individual presenting the prescription (*e.g.*, where a patient repeatedly seeks early refills).

84. One of the key professional responsibilities of a pharmacist, when presented with a prescription for controlled substances, is to identify and resolve any "red flags" before filling the prescription.

85. This pharmacist responsibility—to identify any red flags and resolve them before filling a controlled-substance prescription—is well recognized in the professional field of pharmacy. This responsibility is discussed in the training of pharmacists, by pharmacists at professional conferences, and in training materials prepared by pharmacy boards.

86. This responsibility also has been recognized as an important safeguard against the abuse of controlled substances. For example, in 2014, the National Association of Boards of Pharmacy released a video called "Red Flags," which observed that "by recognizing red flags to help establish the validity of a prescription, the pharmacist becomes the last line of defense in preventing misuse." The video states, "problem prescriptions can often be identified by using common sense, practicing good pharmacy, and looking for red flags that suggest the prescription may not be legitimate."

87. When a pharmacist identifies red flags but is able to resolve them, the pharmacist

has an additional professional responsibility: to document the resolution of the red flags. In other words, pharmacists were trained that, when presented with a controlled-substance prescription bearing a significant red flag, they needed—as part of the usual course of professional pharmacy practice—to investigate and either (a) resolve the red flag before dispensing *and* document the resolution, or (b) refuse to fill the prescription. The documentation ensures that the information about the red flag and its resolution is available for future reference, and the absence of documentation can indicate that the pharmacist did not successfully resolve the red flag.

88. Because this obligation—to identify any red flags relating to a prescription for controlled substances, to resolve them before filling the prescription, and to document any resolution of red flags—is a well-recognized responsibility of a pharmacist in the professional practice of pharmacy, failing to fulfill this responsibility is a violation of 21 C.F.R. § 1306.06, which requires that a pharmacist's conduct, when filling controlled-substance prescriptions, must adhere to the usual course of his or her professional practice as a pharmacist.

3. Violations of these dispensing rules subject the pharmacy to civil penalties and other appropriate relief.

89. The CSA makes it unlawful "for any *person* … subject to the requirements of Part C [21 U.S.C. §§ 821–32] to distribute or dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1) (emphasis added). A person dispensing controlled substances not in compliance with any of the three requirements identified above violates 21 U.S.C. § 829 and thus 21 U.SC. § 842(a)(1).

90. In general, under the CSA, a person is liable for a civil penalty for each violation of 21 U.S.C. § 842(a)(1) regardless of whether the violation was committed knowingly. *Compare* 21 U.S.C. § 842(c)(1)(A) ("any person who violates this section shall … be subject to a civil penalty") *with* 21 U.S.C. § 842(c)(2)(A) (providing that a person who "knowingly" commits

a violation of § 842 may be prosecuted criminally).

91. The Attorney General has provided, through regulation, that a person is liable for penalties for violations of § 1306.04(a) relating to filling prescriptions only where the person violates that rule "knowingly." 21 U.S.C. § 1306.04(a) ("the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."). Accordingly, a person is liable for a civil penalty for violating § 1306.04(a) only if that person "knowingly" filled a prescription that was (1) issued by a medical practitioner not adhering to the usual course of his or her professional practice, or (2) not for a legitimate medical purpose.

92. In contrast, 21 C.F.R. § 1306.06—requiring that the pharmacist's conduct must adhere to the usual course of his or her professional practice as a pharmacist—does not require a showing of a "knowing" violation.

93. The CSA provides that a person who violates 21 U.S.C. § 842(a)(1) shall, with respect to any such violation, be subject to a civil penalty not to exceed $25,000 for each violation on or before November 2, 2015, and not to exceed $67,627 for each violation after November 2, 2015. *See* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.

94. When a corporation's agents or employees violate the rules for dispensing controlled substances, the corporate entity may be held liable for the civil penalty. Corporations must comply with the CSA when they engage in activities covered by the CSA or its implementing regulations, such as operating a pharmacy that dispenses controlled substances. *See* 21 U.S.C. §§ 822(b), 823(f). While the CSA, in 21 U.S.C. § 842(a)(1) and (c)(1), makes a "person" liable for civil penalties, a corporate entity may be the "person" that fills prescriptions through its agents, as the CSA's regulations expressly define "person" to include corporations.

See 21 C.F.R. §§ 1300.01, 1306.02.

95. The CSA also authorizes the Attorney General to seek "appropriate declaratory and injunctive relief relating to violations of … section 842 … of this title," 21 U.S.C. § 843(f)(1), and permits the Court to issue an order "tailored to restrain violations of … section 842 of this title." 21 U.S.C. § 843(f)(3).

D. Distributors must abide by certain legal obligations when they receive controlled-substance orders from pharmacies.

96. The CSA defines a "distributor" as a person or an entity that delivers (other than by administering or dispensing) a controlled substance. The CSA defines "delivery" as the "actual, constructive, or attempted transfer of a controlled substance…." *See* 21 U.S.C. §§ 802(8), (11).

97. Many pharmacies obtain controlled substances from independent distributors, but Walmart—as noted above—served as its own drug distributor until 2018, and operated several dedicated distribution facilities during the Distribution Violations Period.

98. Distributors of controlled substances are required by the CSA to register with DEA and to maintain effective controls against the diversion of controlled substances for illegitimate uses. *See* 21 U.S.C. § 823(b)(1) (requiring the Attorney General, in registering a distributor, to consider whether the distributor has shown "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

1. Distributors must detect and report suspicious orders.

99. Under the CSA, it is unlawful for a distributor to distribute a controlled substance "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a) ("Except as authorized by this

subchapter, it shall be unlawful for any person knowingly or intentionally (1) to . . . distribute . . . a controlled substance").

100. The CSA provides the Attorney General broad authority to "promulgate and enforce any rules, regulations and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b); *see also* 21 U.S.C. § 821 ("The Attorney General is authorized to promulgate rules and regulations …. relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances…"). The Attorney General has issued numerous regulations establishing an extensive regulatory regime. *See* 21 C.F.R. §§ 1300.01-1321.01.

101. The Attorney General, by regulation, has long required distributors to design and operate a system to detect suspicious orders of controlled substances, and to report those orders to DEA. *See* 21 C.F.R. § 1301.74(b). This provision reads, in full: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* In other words, orders that are unusual in one of those three ways—size, pattern, or frequency—are deemed "suspicious orders," and a distributor must detect and report them to DEA. "Suspicious orders," however, are not limited to those three categories, which are non-exclusive.

2. Failure to report suspicious orders subjects the distributor to civil penalties.

102. If a distributor fails to detect and report a suspicious order, it violates the law. Under 21 U.S.C. § 842(a)(5), it is unlawful for any person, including a distributor, "to refuse or negligently fail to make, keep, or furnish any record, report, notification, … or information

required under this subchapter…."

103. A distributor is liable for a civil penalty for each violation of 21 U.S.C. § 842(a)(5) regardless of whether the violation was committed knowingly. *Contrast* 21 U.S.C. § 842(c)(1)(A) ("any person who violates this section shall … be subject to a civil penalty") *with* 21 U.S.C. § 842(c)(2)(A) (providing that a person who "knowingly" commits a violation of § 842 may be prosecuted criminally).

104. The CSA provides that a person who violates 21 U.S.C. § 842(a)(5) shall, with respect to any such violation, be subject to a civil penalty not to exceed $10,000 for each violation on or before November 2, 2015, and not to exceed $15,691 for each violation after November 2, 2015. *See* 21 U.S.C. § 842(c)(1)(A), (B); 28 C.F.R. § 85.5.

II. WALMART, AS A PHARMACY, VIOLATED THE CSA.

105. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart violated the CSA's dispensing rules on a sweeping national scale, filling enormous numbers of invalid controlled-substance prescriptions.

106. These numerous, widespread dispensing violations were the inevitable result of Walmart's failure to take seriously its duty to comply with its CSA obligations, and of the ways Walmart made it difficult for its pharmacists to fulfill those compliance obligations. As discussed below in Part II.A, Walmart pressured its pharmacists to fill prescriptions as fast as possible, leaving them little time to take the steps needed to determine whether controlled-substance prescriptions were valid. While Walmart compiled "red-flag" information about problem prescribers, it did not alert its pharmacists to this information, even though they needed that information to determine whether prescriptions were valid. Walmart also deprived its pharmacists of the tools and support they needed in order to comply with their dispensing

obligations.

107. Walmart knew that many controlled-substance prescriptions it filled were not issued for a legitimate medical purpose, or were not issued in the usual course of professional medical practice, or both. Walmart, through its agents and employees, gained this knowledge in a number of ways.

108. First, on many occasions, Walmart filled prescriptions written by prescribers its own pharmacists repeatedly had identified as problem or even "pill-mill" prescribers. Pharmacists identified specific red flags that they had found unresolvable, and that had led them to refuse to fill prescriptions as invalid and to distrust any prescriptions written by the prescribers. Pharmacists reported these pill-mill prescribers through "refusal-to-fill" forms and other direct communications that they submitted to Walmart's compliance unit, which operated from the company's Home Office and oversaw nationwide dispensing operations. Walmart's compliance unit managers collected and compiled this red-flag information but then chose not to alert other pharmacists to this red-flag information for their use in assessing the validity of prescriptions. *See* Part II.B below.

109. Second, on their face, certain prescriptions presented obvious red flags relating to the amount, dose, or combination of drugs prescribed, or the prescribing patterns. These prescriptions were so dangerous, and so indicative of prescription drug abuse or other diversion, that Walmart pharmacists would have known the prescriptions had a very high probability of invalidity. *See* Part II.C below.

110. Third, on some occasions, a Walmart pharmacist would determine that a prescription was invalid based on the presence of obvious, unresolved red flags and refuse to fill it. Then another Walmart pharmacist—presented with the same or similar red flags—would fill

the prescription or a similar one for the same patient, under circumstances indicating that the pharmacist had recognized the red flags but filled the prescription without resolving them. *See* Part II.D below.

111. From these unresolved red flags, Walmart became aware that it was routinely being asked to fill prescriptions that were not issued for a legitimate medical purpose and/or that were written by prescribers not acting in the usual course of their professional practice. In filling such prescriptions, Walmart thus violated one or both requirements of 21 C.F.R. § 1306.04(a).

112. Walmart also violated 21 C.F.R. § 1306.06 because, in filling numerous controlled-substance prescriptions despite the obvious red flags, Walmart pharmacists failed to comply with their own professional pharmacy practice standards. In many instances they failed to resolve the red flags, and, upon information and belief, also failed to document any resolution of the red flags.

A. Walmart impeded its pharmacists' ability to comply with the legal requirements for dispensing controlled substances.

1. Walmart managers pressured pharmacists to fill prescriptions as quickly as possible.

113. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart pharmacies typically were staffed by a pharmacy manager (a pharmacist), line pharmacists, and pharmacy technicians. Pharmacy managers reported to market directors, who oversaw multiple pharmacies. Market directors reported to market managers, who were responsible for multiple areas of operation. Walmart's pharmacies ultimately reported to corporate executives in the Health and Wellness Division at Walmart's Home Office in Bentonville, Arkansas.

114. Retailers like Walmart operate pharmacies primarily to draw customers into their stores with the expectation that those customers will buy other, non-pharmacy goods. For

example, Walmart observed in its fiscal year 2017 annual report that risks to its pharmacy business could "result in the loss of cross-store or -club selling opportunities and, in turn, adversely affect our overall net sales, other results of operations, cash flows and liquidity." In another example, Sam's Club at times offered drastic discounts on opioids that helped drive customer traffic to its stores.

115. To retain customers, Walmart managers repeatedly told pharmacists to fill prescriptions as quickly as possible. For example, a December 17, 2014 email to certain pharmacists stated that "shorter wait times keep patients in store." Other emails urged that if prescriptions were not filled quickly, customers would shop elsewhere.

116. Even though Walmart pharmacists had legal requirements to satisfy before they could fill controlled-substance prescriptions, Walmart managers told pharmacists to "[h]ustle to the customer, hustle from station to station" because filling prescriptions "is a battle of seconds."

117. Managers sent the pharmacists data showing the previous day's prescription volumes and wait times, and the managers used this data to create competition among pharmacies. Managers ranked stores for the volumes of prescriptions filled and congratulated pharmacists when the pharmacy dispensed high volumes.

118. In various emails, Walmart Health and Wellness Directors set a goal for pharmacists to fill prescriptions in less than 20 minutes—a goal that they later shortened to less than 15 minutes. When pharmacists pointed out the steps required to fill prescriptions, the directors stated that pharmacists should complete all the necessary procedures in 15 minutes or less.

119. Walmart also adopted, as early as 2013, plans for pharmacies, called Pharmacy Facility Management Incentive Plans, that used the number of prescriptions filled by a pharmacy

employee's store as a factor in determining whether the pharmacy employee was entitled to monetary incentive awards.

120. Walmart pharmacists reported feeling unable to do their jobs properly because Walmart pharmacies lacked sufficient staff and the company added resources only when the situation became unmanageable.

121. In addition, Walmart conducted surveys of many of its pharmacy employees in June 2012, July 2014, and October 2014. In response, a substantial number of pharmacy employees reported that their pharmacy lacked sufficient staff to handle the workload. For example, in June 2012, only 59% of the employees reported having sufficient staff to handle the workload. By October 2014, only 43% reported having sufficient staff. In both the June 2012 and October 2014 surveys, a substantial proportion of pharmacy employees reported that they felt rushed with processing prescriptions.

122. Many pharmacy employees responded to the surveys with specific written pleas for more staffing and time to carry out their duties in filling prescriptions. For example, in response to the October 2014 survey, pharmacy employees reported:

- "We are not adequately staffed for safely filling the volume of prescriptions that are brought to this pharmacy. We are spread too thin…."
- "[W]e do not have enough pharmacist help. I feel overwhelmed and like we are being asked to do more and more…. We are being forced to not focus on the patients in front of us…."
- "More bodies in the pharmacy are required to adequately serve our patients, both in a timely and safe manner."
- "[Staffing] is too low for a pharmacy and is dangerous for patients if the staff always

feels overwhelmed or rushed while working on patients [sic] prescriptions."

- "Since … new Control Class II Change for Hydrocodone we have been added more responsibility and time consuming tasks, but our allotted hours for pharmacy staff has not changed…. [T]his can add to pharmacy staff being more rushed to fill Rx, therefore more chance of mistakes happening in the pharmacy." (Emphasis omitted.)
- "Inadequate staffing is a big safety issue as it results in each person juggling more than they should, and opens up the potential for mistakes to occur as a result."
- "We are always under staff[.] [sic] This pharmacy is in [a] busy location, we do a lot of CII [Controlled Substances, Schedule II] and we do have drive thru which takes longer time and needs more staff."
- "I feel that corporately we are expected to get things [sic] too quickly. The expectation times seem unrealistic with the lack of staffing and amount of work we are expected to get done…."
- "I think that someone should come in on a busy day when we do the most scripts and immunizations and just see how we really need man power to ensure safety and accuracy as opposed to not having enough technicians and feeling rushed and behind all the time to save money. One mistake could potentially cost more than it would to have an extra body to keep everything safer and feel less overwhelmed."
- "[Need to] have upper management understand the time constraints with the new cii [Controlled Substance, Schedule II] hydrocodone issues."
- "I have worked for Walmart for over 10 years and generally feel that pharmacist staffing is generally inadequate to provide an environment for a pharmacist to perform tasks in a manner that is truly safe."

- "We don't have enough staff to keep each station caught up at all times. And that is a huge red flag for possible errors."
- "Upper management is totally disengaged over faulty equipment and computer programs that put[s] [prescription] processing at enormous risk—they are culpable! This is coupled with inadequate staffing and poor management support over simple logistical challenges that exceed the pharmacy's ability/authority to resolve."
- "Our [District Manager] continually sends our pharmacy nasty emails and chastises us for not having a [sic] high enough numbers in our input and fill accuracy and times. We are therefore instructed to cheat the system …."
- "[B]ecause of the constant harassment from our market manager about us not getting [prescriptions] done in 20 min, we often take shortcuts in filling and counseling rx's that could lead to patient safety issues."
- "[I]f patient safety is the concern, numbers should not matter more than the patients [sic] health. [M]arket manager and store manager are to [sic] preoccupied with sales and numbers[. T]hey prefer us to rush and get rx out…."
- "I think that professionals need more time to complete the jobs that they were schooled to do."
- "Us being critisized [sic] b[y] our Health and Wellness Director about not getting prescriptions out in 20 minutes causes the pharmacy to take short cuts and affects patient safety." (Emphasis omitted.)

These survey results and the comments were compiled and reviewed at Walmart's Health and Wellness Division.

2. Walmart's compliance unit chose not to give its pharmacists the information and authority it knew they needed to comply with the rules.

123. Walmart's pharmacy operations were part of the company's Health and Wellness Division. The Health and Wellness Division included a compliance team, located at Walmart's Home Office, that was responsible for ensuring that pharmacy operations complied with all relevant federal and state laws. This compliance unit included managers who fielded questions about legal compliance from Walmart's agents in the field, including pharmacists and distribution center staff.

124. Walmart's Health and Wellness compliance unit helped to develop Walmart's internal guidance and procedure documents.

a. Consistent with the CSA, Walmart's own policy required pharmacists to identify and resolve red flags, and to document any resolution of red flags.

125. Walmart's compliance policies regarding its obligations as a pharmacy under the CSA were maintained in a Pharmacy Operations Manual ("POM"), which served as a central resource for its pharmacies at both Walmart and Sam's Club stores.

126. In these policies, Walmart acknowledged that it had to comply with important legal requirements when dispensing controlled substances.

127. In March 2009, Walmart added to its POM a policy ("POM 1311") entitled "Practitioner/Patient Relationship." According to a Senior Director of Pharmacy Professional Services and Government Relations, POM 1311 "provides guidance on the pharmacist's responsibility to ensure that a prescription has been issued for a valid purpose…." The policy thus would serve as a "reference for pharmacists regarding," among other things, "'prescription-mills'."

128. From its inception, POM 1311 provided a non-exhaustive list of factors indicating

when a proper prescriber-patient relationship may not exist. For example, these factors included prescriptions for a large quantity of certain medications or prescriptions with markings suggesting the prescription has been rejected by another pharmacy. The policy also stated that "[i]f the pharmacist does not reasonably believe that a valid prescriber-patient relationship exists, the pharmacist may not dispense the prescription."

129. Walmart issued an amended version of POM 1311 in or about March 2011 that remained in effect at least through January 2014. POM 1311 (2011) identified the same red flags as the prior version and added two more: prescriptions written by an out-of-state prescriber and prescriptions "written by a doctor or for a patient for whom the pharmacy has rejected other prescriptions for a failure to have an appropriate doctor-patient relationship." This list was "by no means all inclusive." POM 1311 (2011).

130. Walmart's POM 1311 (2011) recognized that "federal rules and the laws of many states" require a proper prescriber-patient relationship for a prescription to be valid. The policy acknowledged that pharmacists should not blindly accept a prescriber's assurances: "Simply because the prescriber verifies that he or she has seen the patient does not mean that an 'appropriate' patient prescriber relationship exists; if other signs of an inappropriate relationship are present, the pharmacist can still exercise his or her judgment and not fill the prescription at issue." Similarly, the policy stated that "pharmacists must consider whether the patient and the doctor have a relationship, but the relationship is not valid because it is being used for abuse or diversion."

131. POM 1311 (2011) recognized that a pharmacist should dispense a controlled-substance prescription only if the pharmacist was able to resolve any red flags, and that the pharmacist should document the resolution of those red flags. Under the policy, if a pharmacist

had concerns about a prescription, the pharmacist was permitted to fill the prescription only if the pharmacist "reasonably believe[d]" after speaking with the prescriber that the prescription was valid. In such circumstances, pharmacists still were directed to "make a notation on the prescription specifying" the pharmacist's name, the name of the prescriber, the date of the conversation, and the notation "proper relationship verified."

132. In or about April 2015, as prescription drug abuse continued to escalate throughout the United States, Walmart revised POM 1311 again and specifically addressed pharmacists' obligations with respect to controlled-substance prescriptions, explaining that the CSA imposed a "corresponding responsibility" on pharmacists to dispense controlled-substance prescriptions only if they were written for a legitimate medical purpose and based on a proper prescriber-patient relationship. POM 1311 (2015) quoted directly from 21 C.F.R. § 1306.04 and explained that this regulation was the basis for nearly all criminal actions taken by DEA against pharmacies and pharmacists.

133. POM 1311 (2015) listed several red flags that DEA had identified as signs that a prescription was not issued for a legitimate medical purpose. Walmart acknowledged that red flags could relate to concerns about a prescriber, the prescription itself, or a patient. The red flags Walmart identified included the following:

Prescriber Red Flags:

- Prescription is written by a prescriber outside of the pharmacy's trade area.
- Prescriber routinely prescribes a large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances.
- Prescriber prescribes the same medication, with the same directions, for the

same quantity for a large number of individuals.

- Prescriber routinely writes for large doses of controlled substances.
- Prescriber provides the same diagnosis for the majority of individuals.
- Prescriber engages in the unauthorized practice of medicine, including writing prescriptions outside of scope of practice and/or not having a proper relationship with the patient.

Patient Red Flags:

- Individual insists on paying cash, or insists on paying cash for controlled substances even though insurance is on file.
- Evidence of "doctor shopping" exists.
- Evidence of "pharmacy shopping" exists.
- Individual resides outside of the trade area of [the] pharmacy.
- The individual's statements and conduct or behavior suggest abuse of controlled substances.
- Individual asks for certain drugs prone to abuse by color, trade name or markings and/or uses "street names."
- Individual routinely attempts to obtain an early refill on controlled substances.
- Individuals have suspicious relationships with each other. For example: multiple patients filling prescriptions from one address; prescriptions being presented by someone other than the patient; groups of patients arriving all with prescriptions for the same medication from the same doctor.

Prescription Red Flags:

- Prescriptions presented represent a "cocktail" of commonly abused drugs or

are presented in a combination that can cause medical complications.

- Prescription presented is for an unusually large quantity or high starting dose.
- Prescription appears to be altered or duplicated.
- Prescription has an electronically generated or rubber-stamped signature.

134. POM 1311 (2015) stated that, before a pharmacist filled a controlled-substance prescription with any of these red flags, the red flags "should be evaluated, resolved, and documented." Thus, POM 1311 (2015) shows Walmart's recognition of its legal obligations under the CSA to identify and resolve any red flags, and document the resolution of those red flags, when deciding whether to fill prescriptions for controlled substances.

b. After Walmart was accused of dispensing violations, it committed to adopting a nationwide compliance program to identify red flags and prevent diversion.

135. Walmart, after it faced an enforcement proceeding where DEA accused Walmart of violating its dispensing violations, recognized the need to identify red flags to comply with a pharmacy's dispensing obligations.

136. In March 2011, DEA and Walmart entered into a nationwide memorandum of agreement ("MOA") to resolve an administrative action predicated upon a California Walmart pharmacy's alleged failure to comply with its dispensing obligations when filling controlled-substance prescriptions, including filling such prescriptions where the prescription was not issued for a legitimate medical purpose or by a prescriber acting within the usual course of professional practice.

137. The MOA was in effect from March 2011 through March 2015. In the MOA, Walmart committed to, among other things, "maintain a compliance program, updated as necessary, designed to detect and prevent diversion of controlled substances as required by the

Controlled Substances Act."

138. In the MOA, Walmart recognized that in order to comply with its regulatory obligation not to dispense controlled substances based on prescriptions "issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice …", Walmart needed to create a process that would ensure that its pharmacists were identifying common signs of diversion. Specifically, the MOA required that Walmart's compliance program would include procedures to ensure that pharmacists identified red flags:

> The program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice.

139. In the MOA, Walmart also agreed that if one of its pharmacists did conclude that a prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, was forged, or had been altered, and refused to fill that prescription, Walmart would notify the local DEA field office within seven business days of the refusal to fill.

140. As explained below, Walmart failed to adopt the robust compliance program it had promised DEA it would adopt. It did gather information from its pharmacists as required by its MOA with DEA. But Walmart then took an approach that effectively denied its pharmacists the information they needed in order to comply with their legal obligations when dispensing controlled substances.

c. While Walmart's compliance unit did compile red-flag information, it chose not to disseminate that information to pharmacists.

141. Walmart maintained, in the ordinary course of business, extensive prescription

and dispensing data relevant to determining whether a prescription presented red flags. Indeed, Walmart was obligated to maintain data about dispensing, including the quantities and strengths of controlled substances dispensed. *See* 21 C.F.R. § 1304.22(c).

142. In addition, Walmart's compliance unit received reports submitted by Walmart pharmacists about problematic prescribers or patients. These reports were submitted to the compliance unit via "refusal-to-fill" forms or other direct communications. These reports contained various types of information, such as the name of the prescriber and patient, the prescriber's address and DEA registration number, the controlled substances that had been refused, and the reasons for the refusal. These reports often included, for example, alarming details about pill-mill prescribers whose prescriptions had been refused.

143. As was apparent from Walmart's refusal-to-fill form, some red flags were sufficiently serious that a pharmacist could determine that a prescription was invalid and refuse to fill the prescription without contacting the prescriber. A version of the refusal-to-fill form asked whether the pharmacist had attempted to validate the prescription. If the pharmacist did not attempt validation, the form required the pharmacist to explain how he or she was able to "affirmatively conclude" that a prescription was forged or fraudulent or that there was no valid prescriber-patient relationship. The form thus recognized that there would be instances when a pharmacist could conclude—without contacting the prescriber—that there was no valid prescriber-patient relationship and that the prescriber was thus not acting in accordance with usual medical practice.

144. Walmart pharmacists did determine in many instances that a prescription was invalid based solely on the identity of the prescriber. For example, in December 2013, a pharmacist in North Fort Myers, Florida, concluded that a prescription written by W.W.,

discussed below, was invalid without calling W.W., but based solely on the fact that W.W. "continually writes narcotics" at an office that was "basically a walk in pain clinic."

145. Pharmacists emailed the completed refusal-to-fill forms to Walmart's compliance unit. The emails went to a central email address, which was monitored by a senior compliance manager in the Health and Wellness Division.

146. From 2011 to 2015, during the period when Walmart was under the MOA with DEA and had committed to report refusals to fill, Walmart's compliance unit gathered into a spreadsheet the information it received from the refusal-to-fill forms. Walmart provided some of this information to DEA, though it did so after removing comments from the refusal-to-fill forms, which meant that DEA generally did not see the explanations from pharmacists about why they had refused to fill a prescription.

147. Through these refusal-to-fill forms, Walmart's compliance unit learned about prescribers who were acting as "pill mills" and writing prescriptions for drugs based on patients' drug-seeking requests rather than medical needs, prescribers who were writing prescriptions for the same drugs and dosages for large numbers of patients, prescriptions for "cocktails" of drugs known to be abused, and prescriptions for excessive quantities of controlled substances. Walmart's compliance unit also learned about patients who were hostile and appeared intoxicated or who were doctor and pharmacy "shoppers"—that is, individuals who received prescriptions from multiple doctors and/or filled their prescriptions at multiple pharmacies, to avoid attention to excessive quantities or combinations suggesting abuse. All of these are red flags.

148. Often, the red-flag information contained in the refusal-to-fill forms was not reliably shared—even at the pharmacy level among coworkers. Walmart lacked any effective

process to share red-flag information between pharmacists at the same store who did not have overlapping shifts or with "floating" pharmacists who worked only sporadically at any particular pharmacy.

149. Walmart's compliance unit would have recognized that this information from the refusal-to-fill forms indicated at least a high probability that prescribers were issuing prescriptions that were not for a legitimate medical purpose or were not acting in the usual course of professional conduct. The compliance unit also would have recognized that this information was needed by Walmart pharmacists to carry out their legal and professional obligations to consider and resolve red flags presented by future prescriptions.

150. But, for years, Walmart's compliance unit chose not to disseminate this information to alert pharmacists to the significant volume of red-flag information associated with many of the prescriptions they were being asked to fill. Moreover, Walmart pharmacists knew that Walmart did not have a system that alerted them about the red flags regarding particular prescribers or patients reported to the compliance unit.

151. Walmart's compliance unit could have chosen some method to alert pharmacists to the red-flag information when a related prescription was presented. For example, Walmart's system notified a pharmacist when a medical doctor's license had expired by placing an "edit" in its computer system and by sending out "e-alerts" to its pharmacies to alert them not to fill a doctor's prescriptions. In addition, Walmart's system alerted pharmacists to certain dangerous or deadly drug combinations. But pharmacists were not similarly notified in any way of high-risk prescribers who represented a danger to patients' health.

152. Furthermore, the extremely tight time pressures Walmart placed on pharmacists to fill prescriptions made it impractical, if not impossible, for Walmart pharmacists to learn red-flag

information by contacting Walmart's compliance unit before filling each prescription.

153. For years, Walmart's compliance unit knowingly failed to take necessary steps to ensure that the red-flag information in its possession actually alerted Walmart pharmacists to any red flags they needed to consider. Walmart's compliance unit did not even disseminate such information to pharmacists at Walmart pharmacies that were near the problem prescribers' medical practices or near Walmart pharmacies that had previously refused to fill prescriptions written by problem prescribers.

154. Walmart recognized that individuals presenting prescriptions that were refused by one Walmart pharmacy might try to get them filled at another, nearby Walmart pharmacy. As a Walmart Market Health and Wellness Director observed in May 2014, "these patients and prescriptions will simply move to another location and I was hoping we had a process for flagging doctors that are under investigation so all locations are aware?" A senior manager in Walmart's compliance unit responded that "[t]here is no communication we can put out" and failed to identify any process Walmart had adopted to ensure pharmacists learned of any red flags related to such prescribers.

155. Rather than using the refusal-to-fill forms to ensure that its pharmacists were informed of red flags and could identify invalid prescriptions, Walmart's compliance unit appeared to view the refusal-to-fill forms as useful only for a very narrow purpose: responding to complaints from prescribers or patients about prescriptions that Walmart had refused to fill. As B.N., a senior manager (who in June 2014 became a director) in the compliance unit, explained in an email on March 26, 2013, "The documentation of these refusals is to provide details of the incident for the purposes of supporting the Pharmacists in their decision should any complaint be filed by a prescriber or patient with the Medical Board or Board of Pharmacy." Walmart's

compliance unit routinely used this same boilerplate language in responding to pharmacists who followed up on refusal-to-fill forms—even when those pharmacists raised specific concerns about whether they should continue to fill prescriptions issued by prescribers whose conduct appeared improper.

156. Walmart's compliance unit recognized that its system was not delivering to its pharmacists the information about red flags the pharmacists needed. In 2013, a Walmart "Controlled Substances Work Group" reported that it needed to "[e]stablish a process for the analysis of refusal to fill data and reporting problematic prescribers or patients internally." Also in 2013, Walmart's compliance unit established a "Success Measure" that it would "[d]eliver a process for reporting prescribers or patients internally." The Work Group recognized that, to accomplish this goal, it would need to "[d]etermine how to disseminate refusal to fill decisions and/or problematic prescribers and patients within the same trade area or to the entire corporate entity."

157. Until mid-2015, Walmart did not even have a system that enabled its pharmacists to search for refusal-to-fill information completed by other pharmacists. The only ways a Walmart pharmacist could learn about previous refusals to fill were through word of mouth or by requesting red-flag information from Walmart's compliance unit before filling a prescription.

158. Even though Walmart had committed, under its 2011 MOA with DEA, to "maintain a compliance program, updated as necessary, designed to detect and prevent diversion of controlled substances," Walmart chose for years not to even analyze the red-flag information it collected or to develop a system to disseminate this information to its pharmacists.

159. Instead, Walmart decided to focus on sales. In 2015, B.N., a compliance director, told a vice president in Health and Wellness Operations that during the MOA, the compliance

unit had "not invested a great amount of effort" in data analysis. He explained that "[d]riving sales and patient awareness" was "a far better use of our Market Directors and Market Manager's time."

160. In approximately 2015, Walmart began to make some refusal-to-fill information at least retrievable by other pharmacists. At that time, Walmart introduced a new platform for pharmacy compliance known as "Archer." Walmart pharmacists were instructed to submit refusal-to-fill forms through Archer. With the introduction of Archer, pharmacists were able to search for refusal-to-fill forms submitted by other pharmacists for specific prescribers or patients.

161. But the new Archer system still did not ensure that pharmacists were alerted to red-flag information. Walmart pharmacists were not automatically notified of the adverse information. Nor were they able to review all comments other pharmacists had made on refusal-to-fill forms.

162. Walmart also failed to train pharmacists on the availability and use of these refusal-to-fill forms in Archer. Many Walmart pharmacists did not even know that they could search refusal-to-fill forms. In fact, Walmart did not update POM 1311 until February 2017 to inform its pharmacists that one resource for evaluating and resolving red flags was previous refusal-to-fill documentation in Archer.

163. For most of the Dispensing Violations Period, Walmart's compliance unit generally did nothing to resolve the red flags that had been reported. And by not following up, the company often avoided obtaining readily available information that would have corroborated, rather than resolved, the red flags. For example, Walmart often failed to retrieve relevant information that was accessible from state databases for prescription drug monitoring, from the

public records of state medical licensing boards, and from public criminal records. It also often failed to contact other pharmacies that had decided not to fill prescriptions for a prescriber. In fact, according to some pharmacists, Walmart's compliance unit often did not even take the most basic step of speaking with the pharmacist who had refused to fill the prescription.

164. Upon information and belief, even as of recently, Walmart still had not adopted a system that affirmatively alerts pharmacists, in some way, to the critical red-flag information in a manner that enables its pharmacists to comply with their legal duties. At the same time, Walmart has continued to tout on its website how it has used its pharmacy data to "enhance, customize and optimize the shopping experience" and to "make Walmart pharmacies more efficient."

165. Accordingly, throughout the Dispensing Violations Period, Walmart's compliance unit gathered—through refusal-to-fill forms and other communications—a large volume of red-flag information about numerous high-risk prescribers and patients. But Walmart elected not to take any steps to ensure that its pharmacists received this critical red-flag information that they needed in order to comply with their legal obligations in dispensing controlled substances.

d. Walmart prohibited its pharmacists from refusing to fill, as a blanket matter, all prescriptions issued by pill-mill prescribers.

166. Even when pharmacists determined by themselves that prescribers were acting as pill mills, Walmart's compliance unit refused to let the pharmacists categorically refuse to fill all prescriptions issued by such prescribers. Rather, the compliance unit told pharmacists that they needed to consider each individual prescription—an approach that made it impractical for pharmacists to reject all prescriptions issued by these pill-mill prescribers, particularly given the strict time pressures Walmart imposed on its pharmacists for filling prescriptions.

167. As noted above, in refusal-to-fill forms and other communications, Walmart pharmacists alerted Walmart's compliance unit to prescribers who were acting as "pill-mill"

prescribers and routinely issuing prescriptions not in the usual course of professional practice or not for legitimate medical purposes. Walmart pharmacists repeatedly asked if they could refuse to fill all controlled-substance prescriptions from a problem prescriber operating as a pill mill.

168. In response, Walmart's compliance unit instructed these pharmacists that they were *not* permitted to refuse to fill as a blanket matter. Rather, as B.N. explained in an email, an individual pharmacist was required to operate only on an "individual prescription basis" and no "blanket refusals are allowed."

169. Walmart's compliance unit so often told pharmacists not to impose blanket refusals to fill that managers in Walmart's compliance unit commonly provided this response using boilerplate text pasted into response emails.

170. Walmart's POM 1311 (2011) confirmed Walmart's prohibition on blanket refusals to fill by pharmacists. It stated: "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not based on a valid prescriber-patient relationship or for a valid medical reason before refusing to fill."

171. Walmart's compliance unit also often advised pharmacists that "no blanket refusals are allowed by the Boards of Pharmacy," but—as Walmart's compliance unit knew—this sweeping statement was unsupported. In early 2014, the compliance unit acknowledged its uncertainty when it designated the need "to determine if pharmacists may exercise their discretion to impose blanket refusals" as a "Key Deliverable" it needed to accomplish.

172. In rejecting pleas from its pharmacists that they should be allowed to use their professional judgment to categorically refuse to fill prescriptions, Walmart's compliance unit made clear that a pharmacist was not permitted to determine, in his or her own professional

judgment, that all prescriptions (or certain kinds of controlled-substance prescriptions) issued by a problem prescriber were invalid. Rather, Walmart required the pharmacist to still consider each individual prescription issued by a pill-mill prescriber, and to fill out a refusal-to-fill form for each individual prescription issued by that prescriber.

173. These instructions effectively led Walmart pharmacists to continue to fill prescriptions issued by prescribers whom those Walmart pharmacists had reported as "pill-mill" prescribers because the alternative—filling out a refusal-to-fill form for every prescription issued by a pill-mill prescriber—was impractical. If a pharmacist had to take this prescription-by-prescription approach with a pill-mill prescriber, filling out the refusal-to-fill form for each prescription would consume all the pharmacist's time.

174. For example, as one Walmart pharmacy manager in Texas explained to B.N. in an email on February 6, 2015, "[i]f all of us got together and started filling out refusal to fill" forms for one pill-mill prescriber, "that is all we would do all day long[]. . . ." Stressing how dire the situation was, she reported, "[o]ther chains are refusing to fill for him which makes our burden even greater. Please help us." But the compliance unit still refused to allow the pharmacists to blanket refuse all of that pill-mill prescriber's prescriptions.

175. Later, Walmart began permitting blanket refusals. Walmart also began reviewing problem prescribers in a centralized manner, and began issuing corporate blocks for certain prescribers, preventing any Walmart pharmacist from filling controlled-substance prescriptions issued by those prescribers.

B. Even after Walmart pharmacists identified pill-mill prescribers who were issuing invalid prescriptions, Walmart kept filling their prescriptions.

176. The approach taken by Walmart's compliance unit and managers—pressuring pharmacists to fill high volumes of prescriptions very quickly, while at the same time

withholding from those pharmacists the red-flag information and support they needed to fulfill their gatekeeping duties when dispensing controlled substances—resulted in thousands of violations, all across the country, of Walmart's dispensing obligations.

177. In particular, even after Walmart pharmacists informed the compliance unit about pill-mill prescribers whose practices raised egregious red flags, Walmart continued to fill invalid prescriptions issued by those prescribers, including in some instances prescriptions for the very same controlled substances about which its pharmacists had sounded the alarms.

178. Below are 20 examples of the numerous prescribers whose egregious and unprofessional prescribing practices were known to Walmart. The examples are organized in alphabetical order by the prescribers' initials. In each example, Walmart pharmacists repeatedly recognized, and reported to Walmart's compliance unit, that a particular prescriber was issuing prescriptions without a legitimate medical purpose or outside the usual course of professional practice. In each example, Walmart's compliance unit knew that its pharmacists were continuing to be presented with prescriptions issued by those prescribers, and that, based on the reported red flags, there was a very high probability that the prescribers were regularly issuing invalid controlled-substance prescriptions.

179. In each example, despite possessing this knowledge of red flags, Walmart's compliance unit did not notify its pharmacists of the information the compliance unit had compiled. Nor did Walmart afford any of its pharmacists the time, guidance, and tools they needed to prevent the filling of further invalid prescriptions. Rather, in each example, despite Walmart's knowledge of prescriber red flags indicating a very high probability that the prescriber regularly issued invalid prescriptions for controlled substances, Walmart continued to fill hundreds, and in some cases thousands, of prescriptions by the same problem prescriber.

1. D.C.: "95% of the prescriptions from this prescriber are for controlled substances"

180. D.C. was a doctor of osteopathic medicine who practiced in Wilmington, Delaware.

181. In 2014 and 2015, a Walmart pharmacist at Store 5436 in Wilmington, Delaware, refused to fill prescriptions written by D.C. because he identified unresolved red flags including doctor shopping ("Checked PMP [prescription monitoring program] and saw multiple doctors prescribing similar medications"; "Pt [patient] had received scripts for Percocet from Dr. [C.], Dr. [Y.], and Dr. [W.] in the past two months for 20-30 day supplies") and early refills ("Refilled early too many times … PT says purse was stolen in december leading to an extra fill but could not explain the other fills. Pt had filled Xanax prescriptions 5 times in december and twice in january.").

182. Store 5436 was not the only Walmart location where D.C.'s prescribing habits raised red flags. On May 19, 2016, M.J., Walmart's Director of Controlled Substances, reported to DEA that the pharmacy at Store 3802 in Middletown, Delaware, had placed a suspicious order for oxycodone-acetaminophen 10/325mg. She noted that, even counting all of the prescribers whose prescriptions were filled at that pharmacy, D.C. prescribed 46 percent of the oxycodone-acetaminophen 10/325mg at this pharmacy. Additionally, she noted that 95 percent of the prescriptions from D.C. were for controlled substances, and that 81 percent of what he prescribed was oxycodone-acetaminophen 10/325mg. Finally, she reported that for nearly two-and-a-half years, from January 1, 2014, until May 19, 2016, this pharmacy had not reported a single refusal to fill.

183. Even after M.J. learned that 81 percent of D.C.'s prescriptions were for a single opioid medication at a single strength—oxycodone-acetaminophen 10/325mg—Walmart

pharmacies continued to dispense this same prescription written by D.C. In fact, after the May 2016 suspicious-order report for the pharmacy at Store 3802, Walmart dispensed over 300 oxycodone-acetaminophen 10/325mg prescriptions written by D.C.

184. From May 19, 2016, through July 12, 2017, despite Walmart's knowledge of red flags indicating a very high probability that D.C. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 650 controlled-substance prescriptions written by D.C., including more than 80 where the patient was from a different state than D.C.

185. On August 2, 2019, the Delaware Division of Public Health announced that the Delaware Secretary of State had temporarily suspended D.C.'s medical license and controlled-substance registration, following an investigation by the Delaware Attorney General's Office into his prescribing and treatment practices. The Secretary found that there was an imminent danger to the public health or safety based on the state's serious allegations, which included that D.C. routinely prescribed controlled substances to two undercover officers and eight patients without conducting a meaningful initial evaluation or examination of the patients and without discussing the risks and benefits of using the controlled substances. The state also alleged that he documented physical examinations, complaints, and discussions that had not occurred.

2. F.B.: "Always writes excessive quantities for all of his patients"

186. F.B. was a doctor who practiced at various locations in and around Savannah, Georgia, including a clinic that specialized in footwear for diabetics.

187. As early as June 2012, Walmart pharmacists expressed their concerns about F.B. to Walmart's compliance unit. On June 6, 2012, a Walmart pharmacist working at Store 635 in Savannah, Georgia, refused to fill a prescription for carisoprodol 350mg, reporting that "DR[.] [F.B.] prescribed A MONTH SUPPLY OF controlled drug (NOT a PAIN CLINIC)." In September 2013, a pharmacist at Store 605 in Savannah, Georgia, recognized that F.B. was a

"suspicious md" and that the individual seeking to fill the prescription "currently sees a pain management doc[to]r so she should not be filling [oxycodone-acetaminophen 10/325mg] from this general prac[ti]tioner." The following month, another pharmacist at Store 605 wrote that F.B. was "writing outside of his scope of practice." In 2014, Walmart pharmacists reported that F.B. "is known to write multiple controls for large quant[itie]s" and "always writes excessive quantities for all of his patients."

188. Walmart pharmacists also reported that they refused to fill F.B.'s prescriptions because the customer had refused to wait for a prescription until the pharmacist had contacted F.B. or because F.B. had refused to provide information to the pharmacist. When presented with a controlled-substance prescription where a red flag appears, a pharmacist may attempt to contact the prescriber to determine if the prescription is valid. A patient's unwillingness to wait until such contact has been made and a prescriber's unwillingness to communicate with a pharmacist are additional red flags that can indicate that the prescription is not, in fact, valid. For example, in October 2012, a pharmacist at Store 1024 in Swainsboro, Georgia, refused to fill a prescription for carisoprodol 350mg because F.B.'s DEA registration number was not on the prescription and the individual "refused to wait for me to call during Dr office hours." In numerous instances, beginning as early as February 2013, Walmart pharmacists complained about their inability to contact F.B., writing that "[i]t would be hard to verify the patient prescriber relationship since this office lacks open communication with our pharmacy via phone," F.B. "won[']t return messages to verify rx," and he "is impossible to get in touch with."

189. In February 2014, a pharmacist at Store 4556 in Savannah refused to fill a prescription for customer B.W. for oxycodone-acetaminophen 10/325mg. On the refusal-to-fill form, she recounted a conversation she had had with F.B.: "He asked why I needed to verify a

class 3 narcotic …. When I told [F.B.] that generic Percocet was a class 2 narcotic his response to me was, 'Oxycodone with Acetaminophen is a class 3 narcotic not a class 2 narcotic, you should be ashamed of yourself that you do no[]t know this. I would not have prescribed it if it was a schedule 2 narcotic.' Based upon the fact that [F.B.] is not even aware of the medication he is prescribing (and he prescribes it frequently) I cannot ethically fill the prescription." That same day, however, Walmart filled a prescription for B.W. for alprazolam 4mg, also written by F.B.

190. As other pharmacies in Savannah stopped dispensing F.B.'s prescriptions, individuals turned to Walmart to get them filled. In June 2015, a pharmacist at Store 605 in Savannah observed that "[e]ach weekend – we are beginning to see [an] influx of the same prescriptions written for MANY patients from [F.B.]…. Each weekend, at least 10 patients call/come in pharmacy with Percocet 10/325 #120, Xanax 2 mg #90, Adderall 30mg #90 and sometimes Soma 350mg #90." The pharmacist also told Walmart's compliance unit that "[o]ther pharmacies in our area (ie-Kroger) are no longer taking any of [F.B.'s] prescriptions."

191. From June 26, 2013, through January 2017, despite Walmart's knowledge of red flags indicating a very high probability that F.B. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 500 controlled-substance prescriptions written by F.B. for Medicare patients. Over 200 of those prescriptions were for Schedule II controlled substances.

192. In October 2019, a federal jury convicted F.B. on multiple counts of unlawful dispensing of controlled substances and healthcare fraud. Evidence introduced at trial revealed that F.B. prescribed the "classic trinity" cocktail of opioids, alprazolam, and carisoprodol to

Medicare patients at a higher rate than did any other physician in the United States. F.B. was sentenced to 20 years in prison.

3. F.T.: Prescribed "too many [drugs] for one person to take"

193. F.T., an orthopedist, operated a pain management clinic with offices in Tampa and Punta Gorda, Florida.

194. Evidence of F.T.'s improper prescribing was observed by Walmart pharmacists—and reported up to Walmart's compliance unit—as early as July 2012.

195. Between July 2012 and September 2013, in refusal-to-fill forms to Walmart's compliance unit, Walmart pharmacists reported that they had refused to fill prescriptions after identifying multiple unresolved red flags regarding F.T. For example, pharmacists reported that F.T.'s patients appeared impaired and had used multiple pharmacies, including one individual who had been to more than 10 pharmacies during the preceding year. Pharmacists also identified obvious red flags on the face of the prescriptions, which ordered inappropriate quantities or combinations, such as combinations that posed the risk of respiratory depression and, in one instance, a quantity of Schedule II drugs that was "too many … for one person to take."

196. During that same time period, at least five different pharmacists at different Walmart pharmacies reported, in at least 12 refusal-to-fill forms, that they had refused prescriptions because F.T., the customer, or both were outside the store's area.

197. According to reports from Walmart pharmacists, two different customers told pharmacists in December 2013 and May 2014 that they needed their medications to prevent withdrawals. One of those individuals, who presented a methadone prescription, also had oxycodone in her fill history and presented prescriptions for both herself and her husband. The other customer would frequently come in with several other individuals who, a pharmacist

reported, "always appear high."

198. Reports of F.T.'s inappropriate prescribing practices continued in 2015, with pharmacists reporting, in January and May 2015, prescriptions issued by F.T. for quantities exceeding Walmart's internally set limits for methadone 10mg and inappropriate combinations of opioids and methadone.

199. Walmart continued filling F.T.'s prescriptions. From June 26, 2013, through November 2015, despite Walmart's knowledge of red flags indicating a very high probability that F.T. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 1,000 of F.T.'s controlled-substance prescriptions, including more than 200 prescriptions paid for in cash.

200. In December 2017, F.T. was sentenced to 12 years and seven months in prison after being found guilty at trial of causing the dispensing, without a legitimate medical purpose and not in the usual course of professional practice, of oxycodone, hydromorphone, morphine, and hydrocodone, all Schedule II opioids.

4. G.G.: "gives patients what they want and [does] not practice real medicine."

201. G.G., an osteopathic physician based in Oakland City, Indiana, has a record of criminal and professional misconduct dating back to 2005. That year, the Medical Licensing Board of Indiana suspended his osteopathic physician's license on an emergency basis, finding that he presented a "clear and immediate danger to the public health and safety" because he had allowed an unlicensed individual to prescribe drugs using G.G.'s DEA registration number and to treat G.G.'s patients. G.G. had hired that individual knowing that the individual was not licensed to practice medicine and had paid him $20 per hour.

202. G.G. led his patients to believe that the individual was legitimately practicing

medicine and also led the Medicaid program to believe that G.G. had provided services that were, in fact, provided by the unlicensed employee. For that, G.G. pleaded guilty to Medicaid fraud in 2006. He resolved the Medical Licensing Board action in 2006 by agreeing, among other things, to the indefinite probation of his medical license.

203. G.G. attempted to remove the probationary status from his Indiana license, but the Medical Licensing Board of Indiana denied his petition in October 2015, finding that G.G. prescribed and/or administered controlled substances to patients, including a known drug addict, "outside the safe and generally accepted medical principles and protocols regulating the practice of medicine" and "without objective evidence of medical necessity."

204. While G.G.'s license was in probationary status, Walmart pharmacists learned that other pharmacies in G.G.'s area had imposed a ban on filling his prescriptions. A Walmart pharmacist at Store 2563 in Paoli, Indiana, reported this ban to Walmart's compliance unit in a November 2013 refusal-to-fill form. The pharmacist reported that G.G. had been "[b]anned companywide by CVS and most local pharmacies near where he practices in Oakland City which is nearly 2 hours from this location." The pharmacist also reported in the form that G.G. had a "history of inappropriate practices" and was "on a watchlist with the Office of the Inspector General for the state of Indiana." Another pharmacist from Store 2563 informed Walmart's compliance unit in October 2014 that pharmacies in G.G.'s local area would not fill his prescriptions.

205. On December 10, 2013, G.G. himself stated explicitly to a pharmacist at Store 1263 in Evansville, Indiana, that he prescribed what patients wanted, not what they medically needed. As the pharmacist reported in the refusal-to-fill form: "Doctor declared that he knew it [Ambien 10mg prescription] was above the recommended dose and he couldn't convince the

patient to stop taking it. Doctor wrote the rx due to that[']s what the patient wanted." This refusal to fill occurred at 9:30 a.m. on December 10; on that same day, a different Walmart pharmacy in Evansville (Store 1341) filled a prescription for the same patient for the same drug, zolpidem (of which Ambien is a brand name).

206. Again, in May 2014, a Walmart pharmacist reported to Walmart's compliance unit, through a refusal-to-fill form, that G.G. "gives patients what they want and [does] not practice real medicine." By this time, two Walmart pharmacies, in Evansville and Washington, Indiana, had identified G.G. as a known "pill pusher" or "pill shop doctor," and the pharmacy in Evansville reported that "[b]esides [W]almart no other pharmacies in the tr[i]state will fill for the md."

207. Also in May 2014, a Walmart pharmacist reported to the compliance unit, on a refusal-to-fill form, that G.G. had admitted to an alarming abdication of his professional responsibility: "Dr. [G.G.]. said he does not keep track of patients; he expects us to."

208. G.G. again revealed his disregard for his patients' health when a Walmart pharmacist attempted to validate prescriptions for Adderall and Suboxone (brand name of the drug combination of buprenorphine and naxolone) in September 2014. In a refusal-to-fill form, the pharmacist explained that the patient was getting 30-day supplies of Adderall and Suboxone about every two weeks, all prescribed by G.G. She believed that the "patient looks like they are abusing the meds and the dr doesn't seem to care."

209. The warnings continued into 2015, including one from the pharmacy at Store 870 in Jasper, Indiana, which reported G.G. as a "questionable doctor" and, by February 2015, would no longer would fill G.G.'s prescriptions.

210. Because G.G. prescribed controlled substances based on his patients' desires

rather than any legitimate medical need, Medicaid patients would "flock" to him even though he was not a Medicaid provider, according to a refusal-to-fill form submitted by a Walmart pharmacist in March 2015. And, in return, G.G. got what he wanted: "He charges them [Medicaid patients] cash to give them what they want."

211. From December 1, 2013, through September 2015, despite Walmart's knowledge of red flags indicating a very high probability that G.G. regularly issued invalid prescriptions for controlled substances, Walmart filled over 3,500 controlled-substance prescriptions written by G.G., including approximately 625 paid for in cash and nearly 200 involving a patient from a different state than G.G. and/or the pharmacy.

5. G.H. and R.M.: "well known as a pill mill"

212. G.H. practiced pain management in Roland, Oklahoma. R.M. was the president and medical director of the clinic where G.H. practiced.

213. Walmart pharmacists repeatedly reported that G.H. refused to provide verification for opioid prescriptions. For example, a Walmart pharmacist at the pharmacy in Store 2744 in Fort Smith, Arkansas, reported to Walmart's compliance unit in March and April 2013 that G.H. refused to verify an oxycodone 30mg prescription when contacted and went so far as to block the pharmacy's telephone number.

214. In August 2013, a pharmacist at Store 8 in Morrilton, Arkansas, attempted to contact G.H. to verify an oxycodone 30mg prescription presented by a customer who was seeing multiple doctors and getting prescriptions filled at multiple pharmacies, but the pharmacist did not receive a return call. The pharmacist reported to Walmart's compliance unit that he had learned from another pharmacy in G.H.'s area that the pharmacy routinely turned away his patients because of "questionable prescribing habits."

215. Pharmacists also submitted refusal-to-fill forms to Walmart's compliance unit for

specific prescriptions issued by R.M. These prescriptions, which were presented to pharmacies at Store 380 in Waldron, Arkansas, and Store 55 in Booneville, Arkansas, showed multiple red flags that the pharmacist could not resolve, in that (a) they were written by an out-of-state prescriber; (b) one of R.M.'s patients had just been arrested for "delivery of OxyContin" when he presented a prescription in August 2013 for oxycodone, methadone, and Valium; and (c) a husband and wife both presented prescriptions in April 2014 from R.M. for high doses of controlled substances that presented a significant risk of respiratory depression.

216. By September 2013, a pharmacist who acted as the pharmacy manager at a different Walmart store in Fort Smith, Arkansas, Store 8134, was sufficiently concerned about the prescribing practices of the doctors at R.M.'s clinic that the pharmacist reported to a Walmart market manager in the Health and Wellness Division: "[D]epending on how long it might take co[r]porate to decide on what to do, we might start to refuse to fill prescriptions for some patients. I have too much invested in my career and family to continue to risk it." The pharmacist identified both G.H. and R.M. as the doctors responsible for the clinic's improper prescribing.

217. The market manager forwarded the pharmacy manager's email to Walmart's compliance unit. In reply, B.N., a senior manager in the compliance unit, stated that pharmacists should exercise their independent judgment and refuse a prescription they deem invalid, but he also stated that Walmart had a policy that prohibited a blanket refusal to fill on any particular prescriber.

218. In the same email, B.N., using boilerplate language, explained that the "documentation of these refusals is to provide details of the incident for the purposes of supporting the Pharmacists in their decision should any complaint be filed by a prescriber or

patient with the Medical Board or Board of Pharmacy." B.N. made clear that the refusal-to-fill forms were used by Walmart to protect against future complaints, not to provide other pharmacists with information about prescribers.

219. B.N. explained that he was aware that prescriptions from problematic prescribers would continue to be presented to Walmart pharmacists because "the traffic [to Sam's Clubs] and routines of these patients have already been established" by the "drastic" discounts that Sam's Club once offered for oxycodone.

220. The reports from Walmart pharmacists about the improper prescribing practices of G.H. and R.M. were not shared with pharmacists at other Walmart pharmacies.

221. From September 2013 through June 2014, despite Walmart's knowledge of red flags indicating a very high probability that G.H. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 1,000 of G.H.'s controlled-substance prescriptions, including more than 200 paid for in cash, more than 1,000 dispensed to patients with addresses outside of Oklahoma, and more than 100 written close in time for dangerous combinations.

222. From October 2013 through February 2015, despite Walmart's knowledge of red flags indicating a very high probability that R.M. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 6,500 controlled-substance prescriptions written by R.M. These prescriptions included nearly 600 prescriptions filled between October 2013 and December 2014 by Store 8134, the store that sent the September 2013 email described above.

223. R.M. later admitted that he managed the clinic "like a pill mill that herded patients through the Clinic and prescribed [controlled and dangerous substances] in large quantities based upon little to no physical examination or with no legitimate medical purpose."

224. In 2014, the Oklahoma State Board of Medical Licensure and Supervision filed complaints against G.H. and R.M. As described in the complaints, "[t]he business model of the … Clinic was designed to provide massive amounts of high dose [controlled and dangerous substances] to patients under the veil of a legitimate pain management clinic …. In time, the … Clinic became so well known as a pill mill that people were traveling to it from as far away as Colorado."

225. R.M. voluntarily surrendered his medical license in May 2015, admitting that he prescribed controlled substances for other than legitimate purposes or outside the usual course of professional practice.

226. In July 2015, the Oklahoma State Board of Medical Licensure and Supervision revoked G.H.'s license after an evidentiary hearing finding that, among other things, G.H. engaged in the "indiscriminate or excessive prescribing, dispensing or administering of Controlled or Narcotic drugs."

6. H.D.: "filling for him is a risk that keeps me up at night"; "our concerns are falling upon deaf ears"

227. H.D. was a doctor who practiced in east Texas.

228. Between at least 2011 and 2017, Walmart pharmacies filled large numbers of controlled-substance prescriptions written by H.D.

229. H.D.'s prescribing practices and his patients raised numerous red flags identified in Walmart's own policies and by DEA, including, among others, questionable or repeated drug combinations or "cocktails," excessive quantities of controlled substances, cash-paying patients, and requests for early refills.

230. Beginning no later than 2014, Walmart pharmacists reported to Walmart's compliance unit that H.D. was likely a pill-mill doctor and even enumerated, in writing, the

unresolved red flags associated with his prescribing practices.

231. On February 10, 2014, a Walmart employee emailed a Walmart Market Health and Wellness Director stating that another pharmacy, and possibly Walgreens as well, were "refusing all prescriptions" from H.D. That same day, the email was forwarded to a senior employee with Walmart's compliance unit in Bentonville, Arkansas. The Market Health and Wellness Director stated that the pharmacist brought up "a good point" and asked: "If our competitors will not fill for them, should we stop as well?" The senior employee from Walmart's compliance unit responded that Walmart leaves fill decisions to the pharmacists' "professional judgment" and that Walmart continued "to look at new ideas."

232. Beginning in at least February 2014, Walmart employees received—and relayed to Walmart's compliance unit—numerous warnings that DEA was investigating H.D.'s prescribing practices.

233. On November 23, 2014, an assistant manager at the pharmacy at Store 975 in Durant, Oklahoma, emailed a fellow Walmart employee explaining that "the corporate offices of Target and Kroger have told their pharmacists that they are not allowed to fill [controlled substances] from [H.D.] *at all period*." (Emphasis added.) The assistant manager stated that Kroger's "corporate offices sent out a letter saying that they weren't to fill for him due to some legal issues being investigated with his practice and prescribing and they didn't want their pharmacists 'put at risk' filling these medications *that were not needed and overdosing of his patients*." (Emphasis added.)

234. On February 5, 2015, a Walmart pharmacy manager in Sherman, Texas, sent an email to a Walmart senior director in pharmacy operations, explaining the concern that H.D. "may be a pill mill." The email identified concerning red flags about H.D.'s prescribing

practices, including that he booked patients ten minutes apart, most patients paid with cash, and he refused to answer calls from the pharmacy with questions about prescriptions.

235. The next day, a pharmacy manager from Store 147 in Denison, Texas, sent an email to Walmart's compliance unit about H.D.—copying employees from other Walmart pharmacies—explaining that the situation "has gotten worse," that she and other pharmacists "are all concerned about our jobs and about filling for a pill mill doctor," that her understanding was that other chain pharmacies were refusing to fill prescriptions issued by H.D., and that "I am in my 29th year with [W]almart and have never had a situation this bad with a doctor." The email was then forwarded to B.N., a director in the compliance unit.

236. In an email on February 6, 2015, another Walmart employee at Store 147 commented that at least some of H.D.'s prescriptions were not legal and that "[f]illing for him is a risk that keeps me up at night." Other emails reporting that Walmart pharmacists believed that H.D. was a pill-mill doctor were sent or forwarded to multiple employees at Walmart's compliance unit.

237. Despite the many reports from Walmart pharmacists about H.D.'s egregious prescribing patterns, the compliance unit prohibited those pharmacists from refusing to fill H.D.'s prescriptions as a blanket matter. On December 23, 2014, a pharmacy manager at Store 147 emailed Walmart's compliance unit regarding H.D. and explained that H.D. was "under investigation by the DEA" and that "Walmart is getting slammed with [Schedule II controlled substances] and other control [sic] substances from" him. She further explained that "Target, Walgreens, Kroger, Medicine Shoppe will not honor prescriptions from" H.D. B.N. responded the next day, explaining, in part, that "[b]eing under investigation is simply a red flag to consider when using your professional judgment" and that "an investigation of itself is not a good reason

to discontinue filling legitimate prescriptions." B.N. stated, "[r]emember we are not allowed to blanket refuse to fill for any prescriber." In response, another Walmart pharmacist emailed, stating that while she preferred "to go through the proper channels in situations like this, … it seems as if our concerns are falling upon deaf ears." She warned: "This situation is serious and I am considering contacting the Medical Board/DEA/DPS on my own."

238. Despite all the reports of unresolved red flags, Walmart filled controlled-substance prescriptions written by H.D. for at least three more years.

239. Between February 10, 2014, and March 12, 2017, Walmart pharmacists not only identified red flags associated with H.D.'s prescriptions, but repeatedly appealed to Walmart's compliance unit to address their concerns. But during that period, despite Walmart's knowledge of red flags indicating a very high probability that H.D. regularly issued invalid prescriptions for controlled substances, Walmart filled approximately 14,700 controlled-substance prescriptions (an average of over 13 such prescriptions per day) written by H.D., amounting to over 1,500,000 dosage units. Among many others, Walmart filled the following prescriptions written by H.D. during this period:

- Over 4,800 hydrocodone prescriptions;
- Over 1,170 alprazolam prescriptions;
- Over 1,200 oxycodone prescriptions;
- Over 800 morphine prescriptions; and
- Over 550 fentanyl prescriptions.

240. From 2011 through 2017, approximately 180 different Walmart pharmacies filled controlled-substance prescriptions written by H.D. H.D.'s practice remained in Texas during this period, while these Walmart pharmacies were located in approximately 143 different towns or

cities across 21 different states.

241. On July 6, 2017, a federal grand jury indicted H.D. for CSA violations and other federal crimes. H.D. was later convicted and, in May 2019, was sentenced to 20 years in prison.

242. On July 20, 2017, based on the indictment, the Texas Medical Board temporarily suspended H.D.'s medical license "after determining his continuation in the practice of medicine pose[d] a continuing threat to public welfare" because of the "alleged pattern of practice which includes prescribing dangerous controlled substances with a risk of abuse and diversion for no legitimate medical purpose[.]"

7. J.F.: Prescriber of very heavy doses

243. J.F., an internal medicine doctor, practiced in Silver City, New Mexico.

244. Walmart pharmacists identified, and reported to the compliance unit, unresolved red flags about J.F.'s prescribing, including J.F.'s prescriptions for a highly abused combination of an opioid, a benzodiazepine, and carisoprodol. A pharmacist at Store 4341 in Truth or Consequences, New Mexico, attempted without success to resolve the red flags raised by a prescription for customer T.A. by calling J.F.'s office. The pharmacist reported in a refusal-to-fill form that the pharmacist had called to "confirm the use of Opio[i]d/Soma/Xanax together and discussed the cocktail abusive behavior requested by many patients." J.F.'s staff thanked the pharmacist for bringing the matter to their attention but cancelled the Xanax order, without offering any legitimate medical purpose for the drugs.

245. Nonetheless, the same pharmacy at Store 4341 that had refused to fill the "cocktail" of drugs prescribed by J.F. for T.A. dispensed an opioid, a benzodiazepine, and carisoprodol to T.A. on the same day or one day apart, doing so each month from July through October 2014 and in April and May 2015. Based on the failure of J.F.'s office to provide a medical justification for this combination for T.A., these prescriptions were invalid.

246. Walmart pharmacists also saw that J.F.'s patients engaged in pharmacy and doctor shopping. As early as December 10, 2013, a pharmacist at Store 1357 in Silver City, New Mexico, refused to fill one of J.F.'s prescriptions because, as the pharmacist reported to the compliance unit in a refusal-to-fill form, the patient was "traveling from Las Cruces to see a Dr in Silver City" and the "PMP shows [the patient] is getting narcotics from multiple doctors and filling at multiple pharmacies." Nine days later, the pharmacist refused to fill another prescription for a different patient because, as the pharmacist reported in a refusal-to-fill form, the "PMP showed [the patient] filling at multiple pharmacies and by multiple doctors" and "[u]pon questioning [the patient] revealed he lives in Arizona." The pharmacist submitted additional refusal-to-fill forms for J.F.'s prescriptions in 2014, 2015, and 2016 that reported more instances of pharmacy and doctor shopping by J.F.'s patients.

247. At least seven Walmart pharmacists from six pharmacies in New Mexico submitted refusal-to-fill forms between December 2013 and April 2016 reporting their inability to resolve red flags raised by J.F.'s prescriptions, including that his patients sought early refills, were pharmacy and doctor shoppers, and were suspected of using the drugs for other than legitimate medical purposes.

248. In May 2016, the New Mexico Medical Board summarily suspended J.F.'s license after its investigation revealed egregious conduct reflecting an abandonment of the legitimate practice of medicine. Some of the findings the Board stated in its Notice of Summary Suspension were that J.F. prescribed large dosages of opioids to 680 patients in 2015 alone; prescribed controlled substances to patients from nine states outside New Mexico; prescribed a highly abused combination of controlled substances that is "known to cause fatal drug interactions when prescribed together"; ignored evidence that his patients were abusing and/or

diverting controlled substances; and prescribed multiple controlled substances to a patient who died as "the direct result of toxic effects" from the drugs that J.F. had prescribed. To resolve this action, J.F. voluntarily surrendered his medical license in May 2017.

249. From December 2013, when Walmart pharmacists informed the compliance unit that J.F's patients were seeking early refills and were engaged in pharmacy and doctor shopping, through May 2016, Walmart—despite its knowledge of red flags indicating a very high probability that J.F. regularly issued invalid prescriptions for controlled substances—filled more than 15,000 controlled-substance prescriptions written by J.F., including more than 400 paid for in cash and more than 250 involving a patient from a different state than J.F. and/or the pharmacy.

8. J.I.: A "known pill-mill doctor"

250. J.I. was a pain management doctor in Clearwater, Florida.

251. As early as 2013, several Walmart pharmacists alerted Walmart's compliance unit, through refusal-to-fill forms, that J.I.'s prescribing practices were alarming.

252. From June 2012 through July 2015, Walmart's compliance unit received more than 100 refusal-to-fill forms about J.I. and learned that J.I. prescribed opioids in excessive amounts and in dangerous combinations with other opioids, amphetamines, benzodiazepines, and muscle relaxers.

253. Refusal-to-fill forms submitted in 2014 repeatedly warned Walmart's compliance unit that J.I.'s prescribing practices were "questionable." For example, a pharmacist at Store 1712 in Largo, Florida, reported in a refusal-to-fill form dated April 3, 2014, that J.I. was a "known pill-mill doctor" and then reported in August 2014 that she was a "MILL PILL DR [sic]."

254. Walmart pharmacists also alerted Walmart's compliance unit that J.I. had a public

history of actions taken against her by regulatory authorities based on improper controlled-substance prescribing. In July 2013, April 2014, and July 2015, three different pharmacists in three different Florida Walmart pharmacies refused to fill prescriptions issued by J.I. The pharmacists reported on the forms that J.I. had "previous issues with dea," that she was a "very questionable doctor who has been investigated and suspended previously," and that there were "3 complaints under prescriber's license for CII [Schedule II controlled substances] prescribing." Specifically, DEA had revoked J.I.'s registration in 2006 after she prescribed controlled substances to three undercover law enforcement officers who had admitted to her that they actually were not suffering from any pain. Her registration later was restored, but she was required for a period of one year to provide DEA with monthly reports about her controlled-substance prescriptions. In three separate administrative complaints filed in 2013, the Florida Department of Health alleged that J.I. prescribed excessive and/or inappropriate amounts of opioids without adequate justification.

255. Walmart's compliance unit did not provide any of this information to its pharmacists, who continued to fill prescriptions written by J.I. From July 2013 through March 2017, despite Walmart's knowledge of red flags indicating a very high probability that J.I. regularly issued invalid prescriptions for controlled substances, Walmart dispensed more than 8,000 controlled-substance prescriptions written by J.I., including more than 1,000 that were paid for in cash and more than 100 that raised significant red flags on the face of the prescription based on their dangerous combinations.

256. J.I. pleaded guilty in September 2018 to federal healthcare fraud charges, admitting that she wrote prescriptions, including prescriptions for controlled substances, in the name of certain individuals but then gave the prescriptions to their family members, never

having seen or examined the individuals J.I. knew would be the ultimate users of the drugs. She was sentenced to six months of imprisonment and permanently surrendered her medical license and DEA registration.

9. M.L.: "continually writes for high quantities of narcotics"

257. M.L. was a nurse practitioner who practiced at a pain clinic in Colorado Springs, Colorado.

258. In September 2013, a Walmart pharmacist at Store 3582 in Colorado Springs reported M.L.'s inappropriate prescribing to Walmart's compliance unit. The pharmacist faxed an M.L. prescription to Walmart's compliance unit and submitted a refusal-to-fill form explaining that M.L. "continually writes for high quantities of narcotics." The rejected prescription was for a huge amount: 600 tablets of oxycodone 30mg, providing up to 20 tablets per day, which exceeded a daily limit set by Walmart as a computerized "edit" that alerted pharmacists when a certain threshold was exceeded.

259. Walmart pharmacists repeatedly reported that, when M.L. was contacted about problematic prescriptions, he failed to justify the prescriptions.

260. On March 6, 2015, a Walmart pharmacist at Store 3582 in Colorado Springs refused to fill an oxycodone 30mg prescription after speaking with someone in M.L's office who was able to provide only "nonspecific" answers to questions about the existence of a treatment plan or the consideration of treatment options for the patient. But it does not appear that Walmart provided any alert to other pharmacies about this refusal to fill. And just three days later, on March 9, a nearby Walmart pharmacy at Store 4335 in Falcon, Colorado, dispensed 360 tablets of oxycodone 30mg for the same patient based on a prescription from M.L.

261. Two months later, in May 2015, a Walmart pharmacist at Store 3582 in Colorado Springs spoke with M.L. by telephone, informing him that three Walmart pharmacists were

uncomfortable filling a prescription for the same patient due to the high quantity of oxycodone 30mg (15 tablets per day). M.L. failed to offer any justification, but responded simply "ok." By May 2015, Walmart already had filled five of M.L.'s prescriptions for oxycodone 30mg for this same patient, and each prescription was for a very large amount of oxycodone—300 to 360 tablets, which would allow the patient to take 8 to 12 tablets every day for 30 days.

262. Between November 2013 and March 2016, despite Walmart's knowledge of red flags indicating a very high probability that M.L. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 5,000 controlled-substance prescriptions issued by M.L. Of those 4,000 prescriptions, more than 400 were for dangerous combinations, including prescriptions for two immediate-release opioids simultaneously or close in time and prescriptions for dangerous and abused "cocktails" of drugs.

263. M.L. had received a January 2013 admonition by the Colorado State Board of Nursing for prescribing "excessive" dosages of OxyContin (a brand name of oxycodone) that were inconsistent with the patient's underlying condition. According to the letter of admonition, the letter became a permanent public portion of M.L.'s record.

264. In January 2017, M.L. surrendered his nursing license and prescribing authority to settle a disciplinary action related to his prescribing habits. He admitted that his treatment plans for 12 of 12 chart-audited patients were "inappropriate," and that he had continued opioid therapy in cases where the patient was not benefitting and despite a patient's violation of an opioid agreement. He also admitted that his documentation was "substandard," in part because it failed to explain his increases in opioid therapy.

10. M.M.: A "known pill mill" who sent his patients to Walmart

265. M.M., a doctor in Orlando, Florida, was arrested in June 2010 in "Operation Pain Killer," as reported in the local press, and charged with illegal trafficking of a dangerous

combination of controlled substances (hydrocodone, oxycodone, carisoprodol, and alprazolam). He pleaded *nolo contendere* in February 2013 to an amended charge of racketeering based on the attempted delivery of hydrocodone.

266. M.M. also faced disciplinary action by the State of Florida. Florida's Department of Health filed multiple administrative complaints in October 2011 and an amended complaint in April 2013, all related to his illegal prescribing habits under the guise of practicing medicine. The allegations included that he prescribed excessive amounts of the highly abused "cocktail" of oxycodone, Soma, and Xanax; prescribed controlled substances without following standard practices such as regular urine screens; and prescribed combinations and quantities without medical justification. He also allegedly let a patient choose her own drugs, wrote prescriptions knowing the patient's intent to distribute the drugs, and lied in his medical records to falsely state that a patient suffered from pain.

267. Because the Florida Department of Health records were public, Walmart's compliance unit learned about the disciplinary action in September 2012. That month, a Walmart pharmacist at Store 943 in Winter Park, Florida, discovered the Department of Health complaints and reported in a refusal-to-fill form on September 24, 2012, that M.M. had "several complaints" on file with the "dept of health."

268. Walmart's compliance unit also was aware of M.M.'s criminal conviction just a few weeks after M.M.'s plea. On February 23, 2013, a pharmacist at Store 5106 in Oviedo, Florida, reported, in a refusal-to-fill form, M.M.'s arrest and plea to racketeering. The pharmacist also reported in the form that he had rejected an oxycodone-acetaminophen prescription written by M.M. This refusal was included in a spreadsheet summary that was sent to B.N., a senior manager in the compliance unit, in April 2013. A Senior Director of Quality

Improvement and Clinical Services was copied on the email and suggested in May 2013 to a Senior Director of Health and Wellness Practice Compliance that they discuss the list of refusals.

269. The same pharmacist who had reported M.M.'s arrest in February 2013 rejected at least 10 additional prescriptions between March 2013 and June 2016, each time citing the criminal action in a refusal-to-fill form. Other Walmart pharmacists also reported M.M.'s criminal charges in refusal-to-fill forms and described him as suspicious.

270. During this same period, even after Walmart pharmacists had informed the compliance unit of M.M.'s criminal conviction and pending Department of Health complaints, Walmart continued to fill thousands of M.M.'s prescriptions.

271. M.M. also failed to justify the medical purpose of a prescription when contacted by a Walmart pharmacist. On October 1, 2014, M.M. spoke with a pharmacist at Store 890 in Orlando, Florida, who had refused a prescription for Tylenol # 4 (a brand name of acetaminophen/codeine phosphate 300/60mg). When the pharmacist explained that the patient spoke with slurred speech and already was on tramadol and Fioricet (a brand name drug containing acetaminophen, butalbital, and caffeine), M.M. did not justify his prescription, as he should have if rejection would deprive the patient of medically necessary medication. Instead, according to the refusal-to-fill form, the "doctor stated it would be my call" after the pharmacist explained the reasons she was refusing to fill the prescription.

272. In October 2015, a pharmacy associate suggested to the compliance unit that Walmart had violated its CSA dispensing obligations by filling M.M.'s prescriptions. The associate reported in an email that the pharmacy in Store 4142 in Orlando had filled 43 prescriptions for Schedule II drugs written by M.M. in less than three months, describing him as a "known pill mill" and citing one of the three Department of Health administrative actions that

were then pending. The associate "believe[d] this is something that should be looked into before the DEA comes knocking on our door." The associate's email was sent or forwarded to a Market Health and Wellness Director, a Corporate Compliance Director, a Controlled Substances Director, and B.N., also a Director of Corporate Compliance.

273. M.M.'s prescribing habits were so clearly outside the usual course of professional practice that Walmart pharmacists were told that non-Walmart pharmacies had stopped filling his prescriptions. On January 22, 2016, a pharmacist at Store 2881 in Kissimmee, Florida, reported in a refusal-to-fill form that a patient had asked the pharmacist where he could go to fill the prescription. The patient said that M.M. had instructed him not to take his prescription to Publix, Target, Walgreens, or Winn Dixie, but said that "[another pharmacy chain] and Walmart were ok." Even after being told that Walmart's major competitors were refusing M.M.'s prescriptions, Walmart filled more than 850 prescriptions from M.M.

274. The above-described reports are just a small sample of all the egregious red flags reported by Walmart pharmacists, who repeatedly told the compliance unit that M.M. wrote prescriptions for illegitimate purposes, without a valid doctor-patient relationship, for inappropriate therapies and excessive quantities, and for a high percentage of controlled substances. The pharmacists also reported other red flags related to his patients, who were doctor and pharmacy shoppers, paid in cash, or sought early refills, and some of whom presented to pharmacies appearing intoxicated.

275. M.M. ultimately declined to contest the allegations in the three administrative complaints against him, leading to his voluntary relinquishment of his medical license, effective April 2016.

276. The volume of refusal-to-fill forms also reflected the consistently egregious

nature of M.M.'s prescribing practices. Walmart's compliance unit received approximately 200 refusal-to-fill forms from Walmart pharmacists at approximately 45 different pharmacies between July 2012 and June 2016.

277. From June 26, 2013, through August 2016, despite Walmart's knowledge of red flags indicating a very high probability that M.M. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 8,000 controlled-substance prescriptions written by M.M. Of those, more than 1,350 were paid for in cash.

11. M.N-A.: "many DEA red flags present"

278. M.N-A. was a neurologist in Charleston, West Virginia.

279. In two refusal-to-fill forms submitted in July 2015, Walmart pharmacists reported that non-Walmart pharmacies near Walmart Store 2036 in South Charleston, West Virginia, had stopped filling M.N-A.'s prescriptions.

280. One of those refusal-to-fill forms also reported many other red flags raised by M.N-A.'s prescriptions: "There were many DEA red flags present which led us to turning the script away such as patient traveling a long distance to the pharmacy, duplication of prescribing habits from physician, patient trying to force the pharmacy to fill the prescription and acting in an [un]usual manner." One of the customers told the Walmart pharmacist that "Rite Aid, Kroger and Larry's Pharmacy" would not fill her prescription. A Rite-Aid pharmacist also spoke directly with a pharmacist at the South Charleston store and reported that Rite-Aid had stopped filling for M.N-A.

281. One of the refusals by a Walmart pharmacist in July 2015 was for a Norco 10/325mg (a brand name of hydrocodone-acetaminophen 10/325mg) prescription for patient V.C. Despite the red flags noted by Store 2036, another Walmart pharmacy in South Charleston, Store 6457, filled M.N-A.'s prescriptions for V.C. for hydrocodone-acetaminophen 10/325mg

every month from August 2015 through May 2016.

282. By February 2017, a Walmart pharmacist at Store 4278 in Quincy, West Virginia, reported to Walmart's compliance unit, including M.J., a director in the compliance unit, that she had decided that all of M.N-A.'s prescriptions should be refused.

283. From July 2015 through July 2018, despite Walmart's knowledge of red flags indicating a very high probability that M.N-A. regularly issued invalid prescriptions for controlled substances, Walmart filled nearly 3,000 controlled-substance prescriptions written by M.N-A.

284. M.N-A. lost his medical license and was criminally convicted as a result of his unlawful prescriptions. The West Virginia Board of Medicine began investigating M.N-A. after 11 of his patients died of drug overdoses. In January 2018, M.N-A. resolved that matter by agreeing to limitations on his prescriptions of opioids, benzodiazepines, and Xanax and agreeing to terminate his pain management practice. Thereafter, in July 2018, M.N-A. was indicted on federal drug trafficking charges. That case was resolved when M.N-A. pleaded guilty to prescribing Schedule II controlled substances without a legitimate medical purpose. In his plea agreement, M.N-A. agreed to permanently surrender his West Virginia medical license. M.N-A. and the West Virginia Board of Medicine effectuated the surrender of his license in an amended consent order filed in August 2020.

12. P.T.: "too many questions regarding the ethics and integrity of this physician"

285. P.T. was an internal medicine doctor practicing in Milford, Delaware.

286. In 2013, pharmacists at Store 1741 in Milford observed that P.T.'s patients traveled long distances to get pain medications from him. For example, on November 26, 2013, a pharmacist refused to fill a prescription for oxycodone and methadone based on unresolved red

flags, explaining, "[p]atient from out of state – never a patient here – Dr. [P.T.] RX-he is not a pain mgmt specialist – Patient unable to give valid reason for needing Rx's." That same day, another pharmacist at Store 1741 refused to fill a prescription for Percocet 7.5/325mg, citing unresolved red flags: "Pt is from MD, travel 45 mins to see Dr [P.T.] and was unable to provide a valid reason why she has to come to DE." Just a few days later, the same pharmacist refused to fill an oxycodone 15mg prescription, citing more unresolved red flags: "Pt is from maryland and have a dr in md but comes to de to see dr [P.T.] for narcotic medicines. Was not able to give me a valid reason why his other primary care dr can not take care of his pain medicine."

287. On January 20, 2014, a pharmacist at Store 1741 in Milford refused to fill a prescription for oxycodone 15mg and identified P.T. as a problem prescriber, writing, "Dr redflag [sic] he says he is pain mgn but he is not and prescribe[s] large number of narcotis [sic] in the area."

288. The very next day, January 21, 2014, a pharmacist from Store 2791 in Georgetown, Delaware, reported in her refusal-to-fill forms that she refused to fill four oxycodone 15mg prescriptions from four different P.T. patients. In each instance, she reported, "I have questions about the ethics and integrity of this physician as well as his doctor patient relationships and prescribing for a legitimate health need."

289. The patients continued to arrive at Store 2791, and the same pharmacist refused to fill on numerous other occasions. Eventually, she expanded her explanation for refusing one of P.T.'s prescriptions, reporting, "I have too many questions regarding the ethics and integrity of this physician. I have concerns about his doctor patient relationships as well as prescribing for a legitimate health need. Red Flags: not pain management and most Rx written for oxycodone 15 mg and methadone 10 mg for same qt and sig. Also, Rx did not have quantity spelled out as

required by law. I let the patient know this as he may have problems filling elsewhere."

290. Despite the clear identification of many unresolved red flags, Walmart continued to fill for P.T. until his DEA registration was surrendered for cause in November 2014. For instance, even after Store 1741 identified P.T. as a "red flag" in January 2014, that pharmacy alone—despite Walmart's knowledge of red flags indicating a very high probability that P.T. regularly issued invalid prescriptions for controlled substances—filled over 150 controlled-substance prescriptions written by P.T., and all Walmart pharmacies filled over 1,000 controlled-substance prescriptions written by P.T.

291. In June 2018, a federal grand jury indicted P.T. for unlawful distribution and dispensing of controlled substances. P.T. is awaiting trial.

13. R.K.: Filling prescriptions from this "pill mill" was "putting pharmacists and Walmart in a bad situation legally"

292. R.K. was a doctor of osteopathic medicine who practiced in Mt. Carmel and Shamokin, Pennsylvania.

293. In 2013 and 2014, Walmart pharmacists at Store 2481 in Coal Township, Pennsylvania, refused to fill prescriptions written by R.K., noting in their refusal-to-fill forms numerous unresolved red flags including therapeutic duplication, R.K.'s writing two prescriptions for the same drug for the same individual four days apart, a patient's residing about 60 miles from R.K.'s location, early refills, cash payment, and a large number of controlled-substance prescriptions in a 30-day time period.

294. On September 23, 2016, a Walmart pharmacist at Store 2481 emailed a Walmart Health and Wellness Director to raise her concerns about R.K., explaining that he "prescribes for oxycodone 30 mg in amounts of 150 [tablets], oxycodone 20 mg 150 [tablets] at a time, oxycodone 10 mg for 360 [tablets], Percocet 5/325 for 240 [tablets] routinely, Percocet 10/325

for 240 [tablets] at a time and norco 5/325 and 10/325 always over 120 [tablets], Xanax 0.5 mg and 1 mg always over 120 [tablets], and adipex and Adderall are usually written together for the same person." Additionally, "[t]hrough the pdmp we find him giving multiple rxs to the same patient for the same drug and they are using different pharmacies." The pharmacist highlighted that "[t]wo pharmacies in town will no longer accept his rxs for narcotics." This email was forwarded up the Walmart corporate chain, including to M.J., a director in the compliance unit.

295. Despite these unresolved red flags, within the next two weeks Walmart filled prescriptions for some of the exact drugs, in large quantities, that the Walmart pharmacist had said were typical for R.K., including 150 tablets of hydrocodone-acetaminophen 10/325mg (brand name Norco) for one individual, 240 tablets of oxycodone-acetaminophen 5/325 (brand name Percocet) for another, and 270 tablets of alprazolam (brand name Xanax) for a third individual.

296. On September 30, 2016, a Walmart pharmacy manager at Store 2535 in Saint Clair, Pennsylvania, emailed a Market Health and Wellness Director to inform her that R.K. "is currently under investigation by the DEA for what we believe is a pill mill operation." The pharmacy manager wrote that "Rite Aid has sent him a blanket denial letter." The pharmacy manager further expressed his belief that "if we continue to accept [R.K.'s] prescriptions we are putting pharmacists and Walmart in a bad situation legally as the levels are beyond normal usage." As a result, he asked Walmart to "consider following suit with blanket denial to protect everyone involved." His request to institute a blanket denial was rejected when the Market Health and Wellness Director forwarded his email to M.J., a director in the compliance unit, and asked for guidance. The director's instructions for the pharmacist were to consider each of R.K.'s prescriptions individually.

297. Despite the numerous warning signs, Walmart, including its pharmacy in Coal Township, Pennsylvania, continued to fill thousands of R.K.'s prescriptions. Since January 1, 2015, Walmart—despite its knowledge of red flags indicating a very high probability that R.K. regularly issued invalid prescriptions for controlled substances—dispensed over 8,000 controlled-substance prescriptions written by R.K. Over 5,000 of those prescriptions were dispensed by Store 2481 in Coal Township, where pharmacists had raised warnings about R.K. in 2013 and 2014.

298. Ultimately, in December 2017, a federal grand jury indicted R.K. in a 19-count indictment charging, among other things, the unlawful distribution and dispensing of controlled substances, including violations of federal drug laws resulting in the death of five patients. R.K. is awaiting trial.

14. R.M.: Prescriptions "are likely not prescribed for ethical purposes"

299. R.M. was a family medicine doctor who practiced in the Miami, Florida, area.

300. On January 2, 2014, a Walmart pharmacist at Store 1590 in Hialeah, Florida (near Miami), refused to fill multiple prescriptions from R.M., each time explaining that R.M.'s prescribing was "questionable." Several months later, this pharmacist refused to fill a prescription because R.M. was "prescribing typical cocktail and consistent pattern of prescribing with all prescriptions brought to pharmacy."

301. R.M.'s patients did not attempt to fill his prescriptions only in the Miami area. They fanned out across the United States, presenting Walmart pharmacies with red-flag prescriptions in many different states. In some cases, Walmart pharmacists refused to fill R.M.'s prescriptions, recognizing that the distances his patients traveled were an unresolved red flag. For example, on January 2, 2014, a Walmart pharmacist at Store 2931 in Salisbury, Maryland, refused to fill one of R.M.'s prescriptions, writing that the "rx is from a doctor in Florida. There

are several instances [where] Rxs came from Florida [and] were misused." The following month, in February 2014, a Walmart pharmacist at Store 1072 in Tifton, Georgia, refused to fill an R.M. prescription, reporting in the refusal-to-fill form unresolved red flags including, among other things, that the patient had acted erratically and changed her story multiple times. Then, in November 2014, a Walmart pharmacist at Store 159 in Columbia, Missouri, refused to fill a prescription written by R.M. because "[p]atient is from Kentucky, doctor from Florida, reason to believe that patient and doctor do not have legitimate relationship."

302. Nevertheless, many Walmart pharmacies continued to fill R.M.'s prescriptions, including pharmacies in Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin.

303. Walmart's dispensing of R.M.'s prescriptions outside of Florida did not reflect isolated incidents. For example, from July 2014 until October 2015, Walmart pharmacies in Utah dispensed 250 Schedule II controlled-substance prescriptions written by R.M., the majority of which were for oxycodone 30mg, the highest strength available. Between December 2013 and July 2015, Walmart pharmacies in Missouri dispensed 67 Schedule II controlled-substance prescriptions, again the majority of which were for oxycodone 30mg. And from June 2014 until November 2015, Walmart pharmacies in Arkansas dispensed 55 of R.M.'s Schedule II controlled-substance prescriptions—39 of those for oxycodone 30mg.

304. On June 24, 2015, a Walmart pharmacist at Store 1828 in Plover, Wisconsin, emailed a Market Health and Wellness Director, providing a "list of patients from Kentucky that have been visiting pharmacies in all of central Wisconsin recently." The employee explained

that the patients "are bringing in prescriptions from [R.M.] in Hialeah, FL … for Oxycodone 30mg, Percocet, Diazepam and Methadone." The pharmacist concluded, "[t]his is just an alert of our assumptions that these prescriptions *are likely not prescribed for ethical purposes*." (Emphasis added.) The email was shared with a Walmart director in the compliance unit.

305. In November 2015, a federal grand jury indicted R.M. for violations of federal controlled-substance laws.

306. Despite Walmart's knowledge of red flags indicating a very high probability that R.M. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 300 controlled-substance prescriptions written by R.M. from June 2015 through May 2016, six months after R.M. had been indicted.

307. In June 2020, R.M. pleaded guilty to conspiracy to dispense and distribute oxycodone.

15. R.P.: "horrendous prescribing practices"; "customers that were under the influence tell me that this doctor will write whatever they want"

308. R.P. was a family medicine doctor in Orlando, Florida.

309. No later than August 2012, Walmart pharmacists had begun to report to Walmart's compliance unit, in refusal-to-fill forms, alarming concerns about R.P.'s controlled-substance prescriptions.

310. For example, in February 2013, a Walmart pharmacist at Store 1374 in Altamonte Springs, Florida, submitted a refusal-to-fill form warning that R.P. was prescribing "multiple large quantity rx to patients indiscriminately all c2 [Schedule II controlled substances] or control only." A few months later, in May 2013, the same pharmacist submitted more warnings about R.P. to Walmart's compliance unit, reporting in refusal-to-fill forms, "do not fill for md" because of "horrendous prescribing practices" in "an accordion of control scripts."

311. In March 2014, a pharmacist at Store 3862 in Holly Hill, Florida, reported having "several customers that were under the influence tell me that this doctor will write whatever they want for them except Percocet." A pharmacist at Store 4332 in Orlando, Florida, likewise reported in February 2014 that R.P. was prescribing drugs not based on legitimate medical purposes but to satisfy his patients' drug habits: "Prescriber[']s writing for all most [sic] all patients the medication the patient ask for it."

312. Many of R.P.'s patients fit a typical pattern of drug seekers who abused or otherwise diverted the drugs and were not true pain patients. They sought early refills, traveled long distances, filled multiple prescriptions from multiple prescribers at multiple pharmacies, did not have a verifiable relationship with R.P., presented forged prescriptions, appeared drugged or drunk, and/or became agitated or verbally abusive when their prescriptions were refused.

313. Walmart pharmacists submitted to the compliance unit a steady stream of more than 50 refusal-to-fill forms about R.P. through at least June 2015.

314. Nevertheless, from June 26, 2013, through August 2018, Walmart—despite its knowledge of red flags indicating a very high probability that R.P. regularly issued invalid prescriptions for controlled substances—filled over 18,000 controlled-substance prescriptions written by R.P., including more than 4,000 that were paid for in cash and more than 500 where the patient was from a different state than R.P. and/or the pharmacy.

315. In March 2018, R.P. was permanently barred by the Florida Board of Medicine from prescribing Schedule I through IV controlled substances; treating any patients for chronic non-malignant pain; and owning, operating, or working at any pain management clinic. The administrative complaint leading to the disciplinary action alleged that R.P. had prescribed controlled substances, including fentanyl, not in the course of professional practice to a patient

who died in 2013 of an overdose from fentanyl toxicity.

16. R.W.: Prescribed "cocktails" and recommended patients fill at Walmart

316. R.W. was a medical doctor who practiced primarily in McKinney, Texas.

317. No later than 2014, Walmart pharmacy managers had notified Walmart's compliance unit, in emails, of alarming, unresolved red flags about R.W.'s prescriptions. Between February and December 2014, three different pharmacy managers at Store 5311 in McKinney, Texas; Store 4906 in McKinney, Texas; and Store 147 in Denison, Texas, reported to various Walmart managers in the compliance unit, including B.N., that R.W.'s prescribing habits had become so concerning that non-Walmart pharmacies in the area had stopped filling his prescriptions and that R.W. was telling his patients to fill their prescriptions at Walmart. In December 2014, one Walmart pharmacy manager reported that four competing pharmacy chains had implemented corporate blocks on filling R.W.'s prescriptions and that three other competing pharmacy chains and three independent pharmacies would fill a prescription from R.W. only after taking additional steps to verify the validity of a prescription.

318. A Walmart pharmacist at Store 947 in Sherman, Texas, reported in a February 2014 refusal-to-fill form that one of R.W.'s patients had attempted to fill a prescription for a drug "cocktail" 20 days early. The patient claimed that his medication had been stolen in a car accident, but the police, whom the pharmacist contacted, could not confirm that claim.

319. From February 2014 through November 2016, despite Walmart's knowledge of red flags indicating a very high probability that R.W. regularly issued invalid prescriptions for controlled substances, Walmart filled more than 9,000 controlled-substance prescriptions written by R.W. Of the more than 9,000 prescriptions from R.W. that Walmart filled, more than 700 were paid for in cash.

320. Many of these controlled-substance prescriptions were alarming, as confirmed by a Walmart pharmacy employee who was interviewed by DEA agents in December 2016, when a search warrant was executed at the pharmacy in Store 206 in McKinney, Texas. The employee observed that the number of R.W.'s prescriptions filled by her pharmacy had significantly increased from 2014 to 2016, while competitor pharmacies had stopped filling R.W.'s prescriptions. She stated that she had observed multiple red flags in R.W.'s prescribing habits: prescriptions for "cocktails" of drugs that she knew were abused, high-dose opioids for long periods of time, and excessive quantities of opioids. She also stated that she believed several of R.W.'s patients did not need the medications for medical purposes, based on their disruptive behavior, including their complaints that they could not get early refills and their demands that they needed their medications "NOW!"

321. A pharmacist who also was interviewed during the same DEA search told DEA agents that, in retrospect, she would not have filled several of R.W.'s prescriptions. She admitted to continuing to fill his prescriptions despite the concerns triggered by the number of the prescriptions he wrote for the same "cocktail" of drugs, the number of individuals who traveled long distances to get their prescriptions filled at her pharmacy, and the fact that other area pharmacies had stopped filling R.W.'s prescriptions.

322. R.W. was later convicted on federal drug-trafficking charges stemming from his prescriptions for three controlled substances that comprise a commonly abused "cocktail," which were issued outside the usual course of professional practice and without a legitimate medical purpose. R.W. pleaded guilty and was sentenced in February 2018 to 10 years of imprisonment.

17. S.K.: "there is no way that many 25 year olds need 120 to 240 oxycodone per month"

323. S.K. was a medical doctor who practiced in New Bern, North Carolina.

324. As early as March 2013, Walmart pharmacists emailed Walmart's compliance unit to report that S.K.'s prescribing patterns were alarming. A Walmart pharmacist at Store 1300 in New Bern, North Carolina, spoke to and then emailed a Market Health and Wellness Director seeking guidance because "SOP [standard operating procedure] is not enough-they assure patient relationship and provide diagnosis codes, but there is no way that many 25 year olds need 120 to 240 oxycodone per month." Because of S.K.'s egregious prescribing patterns, the pharmacist reported that four competitor pharmacies in the area were no longer accepting S.K.'s prescriptions because they questioned whether there was a "legitimate medical need." The email was sent to a senior director of corporate compliance in the Health and Wellness Division, and then to B.N., a senior manager in the compliance unit, who responded by simply citing the company's refusal-to-fill policy.

325. S.K. began sending patients to more distant pharmacies when local pharmacies started rejecting his prescriptions. Walmart's compliance unit learned about this troubling practice of S.K. in refusal-to-fill forms submitted by Walmart pharmacists between August 2013 and October 2013. In August 2013, a pharmacist at Store 3864 in Jacksonville, North Carolina, about 35 miles from New Bern, reported that a customer said S.K. had "told him to come to our particular store." The next month, a pharmacist at Store 1236 in Goldsboro, North Carolina, more than 50 miles from New Bern, reported that the patient had "let it slip that Walgreens refused to fill the rx" before the patient presented it to Walmart. And in October 2013, a patient admitted to a Walmart pharmacist in Havelock, North Carolina, about 20 miles from New Bern, that "other pharmacies will not fill for this doc[t]or either."

326. In another clear sign that S.K. was not operating a legitimate medical office, a Walmart pharmacist at Store 3825 in Havelock, North Carolina, reported in an October 2013

refusal-to-fill form that S.K.'s office was not open during the day for pharmacists to call for verification. S.K. was, however, available late at night and answered his own phone to validate prescriptions.

327. A Walmart pharmacist at Store 3864 in Jacksonville, North Carolina, recognized that S.K.'s attempts to validate his prescriptions were insufficient because S.K.'s prescribing practices showed unresolved red flags. In a refusal-to-fill form submitted by that pharmacist in August 2013, the pharmacist reported S.K. "is always in the office after hours up to 9 PM to answer the phone himself to say prescriptions are valid." In addition, the patient had driven a long way to the pharmacy and had been to four different pharmacies in the preceding five months.

328. Between July 2013 and July 2015, multiple Walmart pharmacists submitted to the Walmart compliance unit more than 70 refusal-to-fill forms for S.K., listing a catalogue of unresolved red flags, including that S.K. prescribed large quantities of opioids, lacked valid relationships with his patients, and kept odd hours. Other red flags included that some of S.K.'s patients traveled long distances to fill their prescriptions at Walmart; paid in cash; were hostile, including one customer who "demand[ed] narcotics," requiring that security be called; were very irritable or became upset; and were pharmacy shoppers.

329. In July 2014, Walmart's compliance unit was again alerted to reports that S.K. told his patients that other area pharmacies had stopped filling his prescriptions. Specifically, the pharmacist at Store 3864 reported learning that S.K. "tells his patients that only Wal-Mart will fill his prescriptions" and "all other pharmacies in the area refuse to fill for this prescriber."

330. About 40 percent of S.K.'s controlled-substance prescriptions were paid for in cash, another red flag of abuse.

331. From June 26, 2015, through June 2016, Walmart—despite its knowledge of red flags indicating a very high probability that S.K. regularly issued invalid prescriptions for controlled substances—dispensed more than 1,000 controlled-substance prescriptions written by S.K.

332. S.K. was arrested in June 2016 on federal drug-trafficking charges arising from his opioid prescriptions. He was convicted of numerous federal felony charges, including five counts of unlawful prescribing of oxycodone outside the scope of professional practice and without a legitimate medical purpose, and in September 2020, was sentenced to 20 years of imprisonment.

18. V.S.: A "shady doctor" who "writes only controlled medications for every patient"

333. V.S. practiced as a gynecologist in Bradenton, Florida.

334. As early as December 2013, a Walmart pharmacist at Store 528 in Bradenton filled out a refusal-to-fill form alerting Walmart's compliance unit to V.S.'s high-risk prescribing practices, declining to fill a prescription for oxycodone and methadone because the patient was also on Xanax, which in combination with oxycodone and methadone created a "high risk of respiratory depression."

335. In 2014, several Walmart pharmacists alerted Walmart's compliance unit to concerns about V.S.'s prescribing practices. On a refusal-to-fill form submitted in April 2014, a Walmart pharmacist at Store 1171 in Sarasota, Florida, noted the unusual fact that V.S. was a gynecologist working at a pain clinic. In May 2014, the same pharmacist submitted a refusal-to-fill form reporting that V.S.'s therapies did not appear to be individualized and that V.S. "writes only for c-2's," that is, only for Schedule II controlled substances. Similarly, in June 2014, another pharmacist reported that V.S. "writes only controlled medications for every patient

seen." In September 2014, a third pharmacist submitted a refusal-to-fill form describing V.S. as a "[s]hady doctor."

336. Walmart pharmacists further reported that some of V.S.'s patients presented as drug-seekers rather than legitimate pain patients. For example, a Walmart pharmacist at Store 3474 in Bradenton reported in January 2014 that two customers, who were "slurring their words and showed signs of drug seeking behavior/narcotic abuse," arrived together, one with a prescription from V.S. for oxycodone, methadone, Soma, and Valium, a "cocktail of abuse," according to the pharmacist, and the other saying that he also had his medications filled at that pharmacy.

337. Between January and July 2014, Walmart pharmacists from two different Florida pharmacies reported in refusal-to-fill forms that V.S.'s patients appeared "impaired," "glassy eyed," "possibly intoxicated," or "possibly inebriated," or they slurred their speech.

338. Despite the alarming and unresolved red flags identified in these reports, Walmart pharmacies continued to fill large numbers of V.S.'s controlled-substance prescriptions. During the period from January 2014 through January 2018, Walmart—despite its knowledge of red flags indicating a very high probability that V.S. regularly issued invalid prescriptions for controlled substances—filled more than 3,500 of V.S.'s controlled-substance prescriptions, including more than 600 prescriptions paid for in cash.

339. V.S. let his Florida medical license expire in January 2018. In May 2018, a Walmart employee in the compliance unit was notified that V.S. no longer held a state license to practice medicine or an active DEA registration.

19. W.W.: A "pill mill prescriber" for "drug-seekers"

340. W.W. was a doctor who practiced in Fort Myers, Florida.

341. Beginning in 2013, pharmacists at multiple Walmart stores reported egregious

and obvious signs that W.W. was operating a pill mill, as his prescriptions raised red flags that Walmart pharmacists identified and could not resolve.

342. In May 2013, a pharmacist at Store 3417 in Naples, Florida, reported, in a refusal-to-fill form submitted to Walmart's compliance unit, obvious signs that W.W. was operating a pill mill: "History with patients from this office – we get frequent calls seeking this medication [oxycodone 30mg], daily nagging, patients arriving in car loads, hysteria at drop off, patients sitting in parking lot waiting for FedEx to come; will not fill from this office anymore …." Later in 2013, the pharmacy in Store 3417 repeatedly reported, in refusal-to-fill forms, the store's problems with "drug-seekers" coming from W.W.'s office in the "same car at same time for same meds."

343. A pharmacist from another Walmart pharmacy, Store 5321 in Fort Myers, Florida, reported that W.W. was a pill-mill doctor whose prescriptions should not be filled. Three different pharmacists working at this pharmacy submitted a total of at least six refusal-to-fill forms between July 2013 and February 2015 reporting that W.W. was "running a pill mill," was known for doing so, and was "well reputed for over prescribing C-2 narcotics."

344. In December 2013, yet another Walmart pharmacy, located in Store 5391 in Naples, Florida, reported that W.W. was a "know[n] pill mill prescriber in the [F]ort [M]yers area." A pharmacist working at Store 5391 had submitted a refusal-to-fill form earlier that year, in June 2013, reporting the details showing that W.W. was running a pill mill: W.W. accepted only cash; he engaged in pattern prescribing, once for large quantities of oxycodone until he switched to hydromorphone; and he deployed a "newer technique" of splitting prescriptions in half to "give the appearance of smaller quantities being dispensed."

345. Pharmacists from Stores 3417 and 623 reported in at least four refusal-to-fill

forms in 2013 that W.W. "continually prescribes narcotics [and] not much else," and that his patients were doctor and pharmacy shoppers, some of whom appeared "sever[e]ly impaired and high."

346. By March 2014, a pharmacist from yet another Walmart pharmacy, located in Store 987 in Fort Myers, Florida, had concluded that W.W. "does not prescribe for purposes that I feel are legit[i]mate."

347. The Tennessee Board of Medical Examiners revoked W.W.'s medical license on January 30, 2014, as a result of his failure to supervise nursing staff in what the board described as "egregious prescribing habits" related to controlled substances. W.W.'s licenses to practice medicine in Colorado, Kentucky, and Florida were later suspended or revoked.

348. By December 2014, Walmart's compliance unit knew from a refusal-to-fill form submitted by Store 3417 in Naples, Florida, that W.W.'s license had been suspended by two states "due to mishandling of controlled substances." The same pharmacy reported the same red-flag information in January 2015.

349. From June 2013 through June 2015, Walmart—despite its knowledge of red flags indicating a very high probability that W.W. regularly issued invalid prescriptions for controlled substances—filled more than 700 of W.W.'s prescriptions. Of those prescriptions, about 100 were filled from January through June 2015, after Walmart's compliance unit was informed in December 2014 of the suspension of W.W.'s medical license in two states.

20. Z.B.: A "questionable" prescriber sending patients to fill at Walmart

350. Z.B. was an anesthesiologist who operated a pain management clinic in Tampa, Florida.

351. Walmart pharmacists repeatedly informed Walmart's compliance unit, through refusal-to-fill forms, of unresolved red flags indicating that Z.B.'s patients were not legitimate

pain patients. As early as December 2013, a Walmart pharmacist at Store 959 in Bushnell, Florida, reported Z.B. in a refusal-to-fill form as a "questionable" prescriber, after rejecting a prescription for oxycodone and morphine sulfate.

352. In particular, Walmart pharmacists reported to Walmart's compliance unit that Z.B.'s patients appeared to be pharmacy shoppers who brought prescriptions to Walmart because other pharmacies would not fill their prescriptions. For example, a pharmacist from Store 959 reported on a refusal-to-fill form that the individual was "travelling long distance to get rx filled" and "says local pharmacies doesn[']t want to fill his rx."

353. Walmart pharmacists reported to the compliance unit, in at least four additional refusal-to-fill forms submitted in 2014 and 2015 from Store 959, that multiple individuals for whom Z.B. had written prescriptions traveled long distances to the Bushnell pharmacy to get their prescriptions filled.

354. Refusal-to-fill forms submitted from other Walmart pharmacies in 2013 and 2014 similarly alerted Walmart's compliance unit that individuals whose controlled-substance prescriptions were issued by Z.B. were seeking out Walmart pharmacies to fill those prescriptions. For example, one form noted that a Z.B. patient had admitted to a Walmart pharmacist at Store 1245 in Lakeland, Florida, that he was pharmacy shopping. The patient explained that although he lived in Ocala, Florida, and went to a doctor in Tampa, Florida—about 85 miles away—he had come to get his prescription filled in Lakeland on the recommendation of a friend. Pharmacists in Orlando and Ocala also encountered Z.B. patients who had "passed many pharmacies" on the way to fill their prescriptions at Walmart.

355. Between January 2014 and April 2017, Walmart—despite its knowledge of red flags indicating a very high probability that Z.B. regularly issued invalid prescriptions for

controlled substances—dispensed more than 3,000 controlled-substance prescriptions written by Z.B., including more than 500 prescriptions paid for in cash and more than 100 dispensed to a patient from a different state than Z.B. and/or the pharmacy.

356. Z.B. is awaiting trial on federal charges that he caused the dispensing of controlled substances (specifically, oxycodone, methadone, morphine, oxymorphone, and alprazolam) without a legitimate medical purpose and outside the usual course of professional practice.

C. Walmart filled many prescriptions showing, on their face, such glaring red flags that its pharmacists would have known that the prescriptions had a very high probability of being invalid.

357. Walmart pharmacists also dispensed numerous controlled-substance prescriptions exhibiting, on their face, red flags—including the dose or amount prescribed, combination of drugs, or prescribing pattern—that Walmart pharmacists would have recognized as indicating a high probability that the prescriptions were invalid. But on numerous occasions, Walmart pharmacists filled the prescriptions without resolving the red flags. For example, Walmart's compliance unit found repeatedly that prescriptions showing obvious red flags had been filled with no documentation by the pharmacist that the red flags had been resolved. Upon information and belief, this failure by Walmart pharmacists to resolve obvious red flags and document the resolution before filling the prescription occurred frequently, as Walmart pharmacists were subject to enormous pressure to fill prescriptions extremely quickly—as more fully set forth above in paragraphs 115 through 122 above—and received little training before 2018 on how to handle prescriptions raising red flags.

358. Walmart's compliance unit did not take steps that ensured that its pharmacists identified red flags on the face of prescriptions. Walmart had the ability in its software to set computerized "edits" that could alert pharmacists to aspects of a prescription that showed

obvious red flags. But Walmart's compliance unit did not design its system to automatically alert pharmacists to the red flags described below.

359. Moreover, as set forth below, on occasions when Walmart pharmacists did take note of one of the red flags discussed below, the pharmacists concluded that the red flag was not resolvable, *i.e.*, that the prescriptions should be rejected without further inquiry because the prescriptions could not have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

1. Red Flag No. 1: Dangerous combinations of opioids

360. As trained pharmacists were aware, and as Walmart itself recognized in POM 1311 (2015), prescriptions can show obvious red flags on their face when they are "presented in a combination that can cause medical complications" or are "for an unusually large quantity or high starting dose."

361. One combination that presented obvious red flags, but that Walmart pharmacists repeatedly filled, was prescriptions for multiple immediate-release opioids. Immediate-release opioids (in contrast to extended-release or long-acting opioids) release the drugs more quickly into the bloodstream and generally have a shorter analgesic effect than extended-release drugs. Pharmacists would recognize an obvious red flag when multiple prescriptions for immediate-release opioids were presented at the same time or sufficiently close in time that the supplies would have overlapped.

362. Walmart pharmacists filled different varieties of these duplicative prescriptions on the same day or close in time. For example, they filled prescriptions for as many as three immediate-release opioids, prescriptions for two different strengths of immediate-release oxycodone, and prescriptions for both oxycodone and hydromorphone (another immediate-release opioid).

363. By filling duplicative prescriptions for multiple immediate-release opioids, Walmart dispensed, in some cases, opioids that had a sum total morphine milligram equivalent ("MME," a measure of the potency of a dose of opioids) that reached dangerous levels. These prescriptions thus raised the same concern that Walmart acknowledged in POM 1311 (2015) when it included prescriptions for unusually large quantities as a red flag.

364. Some Walmart pharmacists correctly concluded that duplicative prescriptions for multiple immediate-release opioids could and should be rejected without further inquiry. For example, in June 2013, one Walmart pharmacist refused to fill a prescription written by prescriber R.P. for Norco 10/325 (a brand name of hydrocodone-acetaminophen 10/325mg tablets) and Percocet 10/325 (a brand name of oxycodone-acetaminophen 10/325mg) because "both are immediate release and should not be taken together."

365. In April 2015, another Walmart pharmacist, located in Oklahoma, refused to fill a prescription for an immediate-release opioid (oxycodone 15mg) because the individual already had filled another prescription for a different immediate-release opioid. As the pharmacist explained in a refusal-to-fill form, the individual had "already filled an rx for 180 [tablets of] [o]xycodone 30mg at another pharmacy." The pharmacist commented, "I don't know a reason to be on both."

366. These pharmacists recognized that taking multiple drugs that had the same purpose carried medical risks and that substantially all of the corresponding prescriptions were invalid. Nevertheless, between June 2013 and June 2018, Walmart pharmacists filled thousands of prescriptions for multiple immediate-release opioids on the same day or close in time, in some cases for not only two but three or more immediate-release drugs. Moreover, Walmart pharmacists filled many of these multiple-opioid combinations where additional red flags were

present, including that (i) the prescribing patterns continued for multiple months and (ii) the prescriptions were written by problem prescribers (including one or more of those discussed above).

367. As an example, for customer J.R., Walmart dispensed three different types of immediate-release oxycodone (oxycodone in strengths of 15mg, 20mg, and 30mg) every month from April to September 2013, including twice in May 2013. All of those prescriptions were written by G.H., whose pill-mill prescribing is discussed above. The same Walmart pharmacy dispensed all of those drugs to J.R., almost always at the same time. At times, J.R.'s average daily MME was well over 300, more than three times the MME recommended by the Centers for Disease Control ("CDC") in all but the most extreme cases.

368. Walmart pharmacists also repeatedly filled prescriptions for both immediate-release oxycodone 30mg (the highest strength available for immediate-release oxycodone) and immediate-release oxycodone 15mg at the same time or close enough in time that there was significant overlap and, in some cases, did so for multiple months for the same individual.

369. One of the individuals who received this type of duplicative therapy was D.S. Walmart dispensed to D.S. 168 tablets of oxycodone 30mg and 168 tablets of oxycodone 15mg on the same date, nearly every month, from August 2015 until December 2017. In other words, over this period, Walmart dispensed a total of 5,208 tablets of oxycodone 30mg and 5,208 tablets of oxycodone 15mg to D.S. If taken as directed on the prescriptions, these drugs produced a total daily MME of 405—more than four times the recommended CDC maximum in all but the most extreme cases.

370. As another example, for customer D.W., a Walmart pharmacy in Arkansas dispensed oxycodone 30mg (126 to 222 tablets) and oxycodone 15mg (84 to 148 tablets) nearly

every month from January through August 2015. D.W.'s prescriptions were written by an Oklahoma prescriber, J.R. J.R. issued prescriptions for the same duplicative opioids (oxycodone 15mg and 30mg) to two other individuals as well; Walmart filled those prescriptions for at least three months in a row.

371. For other individuals, Walmart pharmacists repeatedly filled prescriptions that were for two different opioids, but nonetheless were duplicative because both drugs were immediate-release. For example, Walmart pharmacists filled prescriptions for both immediate-release oxycodone and immediate-release hydromorphone and, in many cases, for the highest strength available for both medications (30mg in the case of oxycodone and 8mg for hydromorphone).

372. These prescriptions not only were duplicative but also combined a powerful opioid, oxycodone, with an even more powerful one, hydromorphone. One milligram of hydromorphone equates to four MME. By comparison, one milligram of oxycodone equates to one-and-a-half MME.

373. As an example, for customer K.R., Walmart filled more than 20 prescriptions for hydromorphone 8mg and 20 prescriptions for oxycodone 30mg over a 12-month period. K.R. routinely received prescriptions for these two drugs from the same Walmart pharmacy on the same day. All of those prescriptions were written by M.L., whose problematic prescribing is described above. Furthermore, the quantities dispensed were extraordinarily large: at times, had K.R. been taking both drugs as prescribed, K.R.'s daily MME would have exceeded 1,000—more than 10 times the CDC maximum in all but the most extreme cases. In total, over this period, Walmart dispensed 3,960 tablets of oxycodone 30mg and 4,624 tablets of hydromorphone 8mg to K.R.

374. All told, from June 2013 forward, Walmart pharmacists filled thousands of prescriptions for these dangerous combinations of immediate-release opioids. Walmart pharmacists would have known that substantially all of these prescriptions they filled created dangerously duplicative immediate-release opioid combinations and were invalid.

375. Another opioid combination that trained pharmacists recognized as raising obvious red flags on their face was a combination of an immediate-release opioid and methadone, another powerful opioid.

376. Methadone is generally a longer-acting drug. Compared to an immediate-release opioid, it generally takes longer for the user to feel its effects, but those effects may last longer. For this reason, when taken in combination with an immediate-release opioid, methadone can be particularly dangerous; its long-acting properties may lead the user to take higher amounts of immediate-release opioids to achieve the desired euphoria or painkilling effects in the short term, but the long-term depressive effects of methadone can lead to excessive respiratory depression and death when combined with the effects of another opioid.

377. At least one Walmart pharmacist concluded that prescriptions for this combination present an unresolvable red flag. In January 2014, a Walmart pharmacist in Bradenton, Florida, refused to fill a prescription for oxycodone and methadone written by prescriber V.S. because "[m]ethadone should not be taken with other opioids or with benzodiazepines per pain management guidelines and per gold standard [due to] high risk of respiratory depression." The same pharmacist, working in a pharmacy in Sarasota, Florida, refused to fill a prescription for Dilaudid (a brand name of hydromorphone) and methadone written by prescriber F.T. (whose problematic prescribing is described above) in March 2014 for the same reason: "Inappropriate therapy per pain management guidelines, it is not recommended

to take methadone with other opioids [due to] high risk of respiratory depression."

378. Other Walmart pharmacists nonetheless repeatedly filled prescriptions for both an immediate-release opioid and methadone at the same time or close in time. In some instances, Walmart filled these prescriptions for months. In many cases, Walmart pharmacists filled the highest strength available in methadone (10mg), as well as the highest strength available in the immediate-release opioid (for example, oxycodone 30mg).

379. By way of example, for customer C.B., Walmart dispensed at least 240 methadone 10mg tablets plus at least 108 oxycodone 30mg tablets every month from June 2017 to July 2018. The same Walmart pharmacy dispensed all of those drugs to C.B. and always dispensed the methadone and oxycodone together.

380. On the same day that Walmart dispensed those dangerous combinations to C.B., the same Walmart pharmacy dispensed the same dangerous combinations—in the same quantity and days' supply, and based on prescriptions written by the same prescriber—to M.B., who shared the same last name as C.B. and, according to Walmart's own data, lived at the same address.

381. Similarly, during a four-year period from February 2013 through February 2017, and based on prescriptions written by H.D. (whose problematic prescribing is discussed above), Walmart frequently dispensed to customer T.S. 200 or more tablets of methadone 10mg and 100 or more tablets of oxycodone 30mg, which resulted in a combined average of at least 950 MME per day if T.S. took those quantities of drugs together. In November 2013 alone, a Walmart pharmacy dispensed 690 opioid pills to T.S., all in the highest strength available. Specifically, that Walmart pharmacy filled two separate prescriptions for 225 tablets of methadone 10mg and two separate prescriptions for 120 tablets of oxycodone 30mg during that one month.

382. The doses and quantities of opioid painkillers that Walmart regularly dispensed to T.S. from February 2013 to February 2017 appear generally too high for any one person to take, and therefore strongly suggest the pills were being diverted to persons other than T.S. Walmart also dispensed some of those Schedule II drugs early—including eight or more days early on at least two occasions—which further indicates the high probability that those prescriptions were being diverted to others.

383. All told, from June 2013 forward, Walmart pharmacists filled thousands of prescriptions comprising this dangerous opioid-methadone combination. Hundreds of those prescriptions were paid for in cash, and hundreds more were dispensed to individuals who were from a different state than the prescriber or pharmacy. Walmart pharmacists would have known that substantially all of these prescriptions were invalid.

2. Red Flag No. 2: Dangerous "cocktails" of opioids and non-opioids

384. Certain combinations of different types of medications present red flags. As trained pharmacists were aware, and as Walmart itself recognized in POM 1311 (2015), red flags include prescriptions "that represent a 'cocktail' of commonly abused drugs." A compliance unit director explained in an internal email in February 2016 that "[a] cocktail is a red flag that should alert the [pharmacist] to use their professional judgment to refuse to fill the [prescription]."

385. These combinations included not only duplicative opioids, but also other dangerous combinations including an opioid and other, non-opioid "potentiator" drugs—that is, drugs that increased the euphoric effect brought on by opioids, but that also increased the risk of abuse and overdose. These dangerous opioid/non-opioid "cocktails" signaled abuse and indicated that substantially all of these particular prescription combinations were illegitimate.

386. Walmart pharmacists filled thousands of prescriptions that fall into four distinct "trinity" categories of combinations of opioid/non-opioid prescriptions that on their face

presented an obvious red flag as to the prescriptions' validity. Each category was known to be popular among individuals who were abusing or misusing prescription drugs.

387. **The classic trinity.** First, Walmart pharmacists repeatedly filled prescription drug cocktails consisting of (a) an opioid; (b) a benzodiazepine; and (c) the muscle-relaxer carisoprodol (brand name Soma). This combination, sometimes referred to as the "classic trinity," had been described in DEA administrative decisions as early as 2008. Specifically, the three drugs taken together produce enhanced euphoric effects beyond the effect of the individual drug. For similar reasons, however, the classic-trinity combination creates a heightened risk of overdose and death.

388. Walmart pharmacists filled many of these "classic trinity" drug cocktails when the three drugs were filled either at the same time or with significant overlap and where additional red flags were present, including, among other things, (i) where a significant supply was prescribed for each drug; and (ii) when the filling pattern for the combination continued for multiple months.

389. Some of these "classic trinity" prescriptions also were written by problem prescribers, such as those described above. By way of example, S.F. was a patient of J.I., whose problematic prescribing and pill-mill activity are described above. Pharmacists at Store 1712 in Largo, Florida—the same pharmacy that identified J.I. as a "MILL PILL DR [sic]"—dispensed "classic trinity" cocktails to S.F. based on prescriptions from J.I. nearly every month for three years between February 2014 and February 2017. More than half of the time, Walmart dispensed *both* 120 pills of hydrocodone-acetaminophen 10/325mg (*i.e.*, Vicodin) *and* 60 pills of morphine sulfate extended release, *in addition* to the potentiating benzodiazepines and muscle relaxers.

390. Another instance involved a "classic trinity" prescription written by J.F., whose problematic prescribing is described above. A pharmacist at Store 4341 in Truth or Consequences, New Mexico, dispensed an opioid, a benzodiazepine, and carisoprodol to customer T.A. on the same day or one day apart each month from July through October 2014 and in April and May 2015, based on prescriptions written by J.F.

391. **The zolpidem trinity.** Second, Walmart pharmacists repeatedly filled a different, but similarly dangerous, combination, sometimes referred to as the "zolpidem trinity," consisting of (a) an opioid, (b) a benzodiazepine, and (c) the sedative zolpidem (brand name Ambien). The "zolpidem trinity" is dangerous because the addition of a sedative to two other central-nervous-system depressants may lead to accidental overdose.

392. As with the "classic trinity," Walmart pharmacists filled many of these "zolpidem trinity" combinations where additional red flags were present, including, among other things, (i) when such prescriptions were filled either at the same time or with significant overlap, (ii) when a significant supply was prescribed for each drug, or (iii) when the filling pattern for the combination continued for multiple months.

393. Some of these "zolpidem trinity" prescriptions were also issued by problem prescribers, such as those described above. By way of example, from August 2013 to March 2014, Walmart dispensed to customer T.H. "zolpidem trinity" cocktails every month. Those cocktails—all of which were prescribed by H.D., whose pill-mill activity is described above—invariably comprised 120 tablets of oxycodone 30mg, the highest strength of immediate-release oxycodone available; 120 tablets of alprazolam 1mg (*i.e.*, Xanax), the second-highest strength of immediate-release alprazolam available; and 30 tablets of 10mg zolpidem (*i.e.*, Ambien), the highest strength of immediate-release zolpidem available. Each month that Walmart dispensed

those trinity combinations, the same store also gave T.H. 180 tablets of hydrocodone-acetaminophen 10/325mg (*i.e.*, Vicodin). In five of the eight months, Walmart also dispensed 60 tablets of morphine sulfate extended-release 60mg. In other words, every month for eight straight months, Walmart gave T.H. 300-360 opioid pills *in addition to* two potentiating drugs that increase the risk of abuse and overdose.

394. **The stimulant trinity.** Third, Walmart pharmacists repeatedly filled a similarly dangerous drug cocktail sometimes referred to as the "stimulant trinity" or "blackout trinity," consisting of (a) an opioid, (b) a benzodiazepine, and (c) a stimulant. The "stimulant trinity" is dangerous, given that the effects of the stimulant may lead the user to overdose on the opioid and/or the benzodiazepine in an effort to achieve the desired euphoria.

395. Walmart pharmacists repeatedly filled "stimulant trinity" cocktails under circumstances where additional red flags were present, including, among other things, (i) when such prescriptions were filled either at the same time or with significant overlap, (ii) where a significant supply was prescribed for each drug, or (iii) when the filling pattern for the combination continued for multiple months.

396. For example, for customer K.C., Walmart dispensed a "stimulant trinity" every month between March and May 2014, then again almost every month between May 2016 and April 2017. Those cocktails invariably comprised 120 tablets of oxycodone 30mg, 45 tablets of clonazepam 2mg, and 30 tablets of amphetamine-dextroamphetamine 30mg. The same Walmart pharmacy filled all of those prescriptions, frequently on the same day or within a few days of one another. In addition, that same Walmart pharmacy also gave K.C. a second opioid every month.

397. Similarly, for customer J.H., Walmart dispensed a "stimulant trinity" every month from January 2015 to July 2015, all based on prescriptions written by S.L. All of the trinity

combinations that Walmart provided to J.H. were dispensed either on the same day or within a few days of one another, and were often accompanied by additional tablets of extended-release oxycodone 80mg (specifically, for the brand OxyContin). With only two exceptions, all of those pills were dispensed from the same Walmart pharmacy.

398. Another of S.L.'s patients, H.T., received so many opioids, benzodiazepines, stimulants, and sedatives from Walmart between April 2014 and June 2015 that H.T. could make multiple trinity combinations with them nearly every month. There was no apparent legitimate medical need for all of the pills that Walmart dispensed to H.T., and the likely explanation is diversion to other individuals. That Walmart pharmacists, on multiple occasions, dispensed the Schedule II drugs seven or more days early further indicates the invalidity of the prescriptions and supports the inference of diversion.

399. Walmart pharmacists recognized the risks presented by the trinity combinations. A pharmacist at Walmart Store 63 in Wagoner, Oklahoma, refused to fill an oxycodone 30mg prescription on February 19, 2015, because the "dosage and quantity [was] inap[p]ropriate for chronic pain management." The pharmacist also recognized from the information that was available through Walmart's computer system that individual H.T. also had prescriptions for "Soma, Adderall, Ambien, Tramadol, MS Contin, and Xanax," which in combination with the oxycodone, were "potentially dangerous," including possibly leading to "CNS [central nervous system] depression."

400. Nevertheless, four days later, on February 23, 2015, a Walmart pharmacist at Store 374 in Coweta, Oklahoma, filled an oxycodone 30mg prescription that was written on February 18, 2015, dispensing 480 tablets to H.T., enough for H.T. to take 16 tablets every day for 30 days.

401. **The trinity plus.** Fourth, Walmart pharmacists repeatedly dispensed a drug cocktail consisting of (a) two or more different immediate-release opioids (including different strengths of the same opioid); (b) a benzodiazepine; and (c) either carisoprodol or zolpidem. This "trinity plus" combination creates many of the same risks of abuse or overdose as the other "trinity" combinations, but with the addition of another opioid, has an increased risk of abuse, overdose, or death.

402. Walmart pharmacists repeatedly dispensed "trinity plus" drug cocktails under circumstances where additional red flags were present, including, among other things, (i) when the four drugs were filled either at the same time or with significant overlap; (ii) where a significant supply was prescribed for each drug; or (iii) when the filling pattern for the combination continued for multiple months.

403. In addition, "trinity plus" prescriptions were written by problem prescribers. By way of example, in 2017, for customer C.J., Walmart filled prescriptions for a "trinity plus" combination in May, twice in June, and once more in July. Those combinations—which were written by a prescriber whose prescriptions over the years presented what one Walmart pharmacist described as "unresolvable red flags"—invariably included 120 tablets of oxycodone 30mg; 60 or more tablets of hydromorphone 2mg; 90 tablets of lorazepam 1mg; and 60 tablets of carisoprodol 350mg, some of which were paid for in cash even though C.J. was covered by Medicaid.

404. As another example, nearly every month from November 2014 until December 2015, Walmart filled prescriptions for a patient of Oklahoma prescriber J.R. for 30 tablets of zolpidem 10mg, 60 to 90 tablets of alprazolam 2mg, 120 tablets of oxycodone 15mg or 30mg, and 120 tablets of a second opioid—oxycodone-acetaminophen 10/325mg.

405. Similarly, Walmart filled, on a monthly basis, the zolpidem trinity "plus" prescriptions for T.G. of Arkansas from April through December 2014. Specifically, each month Walmart dispensed two opioids—240 tablets of oxycodone 30mg and 240 tablets hydromorphone 40mg, totaling 488 MME per day; 120 tablets of diazepam 10mg; and 30 tablets of zolpidem 10mg. These prescriptions were written by prescriber H.T. of Missouri, for whom such cocktails were not uncommon. A Walmart pharmacist in Joplin, Missouri, refused to fill prescriptions written by H.T. because, among other things, she "routinely writes for a 'cocktail' of commonly abused drugs or combo that can cause medical complications" and she "writes for large doses of controlled substances."

406. More recently, Walmart filled the classic trinity for customer K.M., including two opioids (oxycodone 15mg and hydrocodone-acetaminophen 10/325mg) each month from March until August 2017 and then again from November 2017 until June 2018. These prescriptions were all written by Missouri prescriber P.G.

407. All of these trinity prescriptions, on their face, presented significant red flags that a Walmart pharmacist would have recognized as indicating that the prescription was not issued for a legitimate medical purpose or in the usual course of medical practice. Walmart pharmacists would have known that substantially all of the prescriptions they filled to create dangerous trinity and "trinity plus" combinations were invalid.

408. All told, from June 2013 forward, Walmart pharmacists filled thousands of prescriptions comprising these dangerous trinity combinations, many of which presented additional red flags of abuse or other diversion. Hundreds of them, for instance, were paid for in cash, and hundreds more were dispensed to patients who were from a different state than the prescriber and/or pharmacy.

3. Red Flag No. 3: Repeated fills of very high dosages of opioids

409. As trained pharmacists were aware, and as Walmart recognized in POM 1311 (2015), certain prescriptions presented red flags if they were "for an unusually large quantity or high starting dose." Walmart pharmacists often reported in refusal-to-fill forms that prescriptions for high dosages were a red flag.

410. Nevertheless, for some individuals, Walmart pharmacists repeatedly filled prescriptions for extraordinarily high dosages of potent opioids. For many of those individuals, each opioid prescription resulted in average daily MME many times higher than the CDC-recommended maximum of 90 MME in all but the most extreme cases. In fact, for numerous individuals, Walmart dispensed such high quantities of high-strength opioids that the *average* daily MME across the opioid prescriptions filled by the individual at Walmart exceeded 800 MME.

411. Such high dosages and quantities of opioids are needed only extremely infrequently and are highly unlikely to be prescribed in the usual course of professional treatment except in the treatment of terminal illness. As a result, these prescriptions, on their face, presented an obvious red flag.

412. By way of example, on 16 separate occasions from March 2014 to September 2014, Walmart gave customer M.P. 1,500 tablets of hydrocodone-acetaminophen 10/300mg for a 16-day supply—enough for M.P. to take 93 pills *per day*. Walmart filled all those prescriptions even though each of those prescriptions was written by H.D. (whose pill-mill conduct is described above) and gave M.P. a massive average daily MME of 937, more than 10 times the maximum CDC recommendation in all but the most extreme cases.

413. Similarly, from December 23, 2013, to January 9, 2014, Walmart gave customer S.C. 765 tablets of hydrocodone-acetaminophen 7.5/325mg *plus* 236 tablets of hydrocodone-

acetaminophen 7.5/500mg *plus* 180 tablets of hydrocodone-acetaminophen 10/325mg. Put simply, a single Walmart pharmacy dispensed 1,181 opioid pills to S.C. over the course of only 18 days. On December 23, 2013, alone, Walmart gave S.C. 236 tablets of hydrocodone-acetaminophen 7.5/500mg for a two-day supply—enough pills for S.C. to take 118 *per day*. Given the risk of acetaminophen toxicity or opioid overdose, it is not physically possible to take that many tablets of hydrocodone-acetaminophen 7.5/500mg in such a short period. Walmart dispensed the drugs anyway.

414. For customer D.M., Walmart dispensed excessive quantities of not just one, but three, potent opioids. Specifically, every month from December 2014 to September 2015, Walmart gave D.M. 30 fentanyl 100mcg/hr patches *plus* 450 methadone 10mg pills *plus* 328 to 480 oxycodone 30mg pills. The methadone alone was enough to give D.M. an average daily MME of 1,800, and yet the same Walmart store that dispensed those massive quantities of methadone also gave D.M. fentanyl (an extremely potent opioid) and the highest strength of immediate-release oxycodone available.

415. All told, from June 2013 forward, Walmart pharmacists filled numerous high-MME prescriptions, many of which presented additional red flags of abuse or other diversion. For instance, some of them were paid for in cash, and many more were dispensed to individuals who were from a different state than the prescriber and/or pharmacy. In addition, many of these prescriptions were written by some of the problematic prescribers described above.

416. Thus, Walmart pharmacists would have known that substantially all of the very high-MME prescriptions they filled were illegitimate.

4. Red Flag No. 4: Schedule IIs filled unusually early

417. As trained pharmacists were aware, when an individual requests to fill a controlled-substance prescription significantly early, it raises a red flag regarding abuse or other

diversion because it suggests that the individual is either taking a higher quantity than prescribed or diverting at least some of the pills to other individuals.

418. Walmart repeatedly filled prescriptions for Schedule II controlled substances significantly early, well before the individual should have exhausted the previously dispensed supply from an earlier prescription. These prescriptions were filled so early that they indicate that Walmart pharmacists would have known that substantially all of them were illegitimate.

419. Because a prescription for a given controlled substance requires the dosage, quantity, and directions for use, *see* 21 C.F.R. § 1306.05(a), there is a specific date on which the supply of drugs dispensed pursuant to that prescription will be exhausted. For example, if a prescriber prescribes a drug of a particular dose, directs that it be taken six times per day, and prescribes a total of 180 tablets, the prescription authorizes a 30-day supply of drugs for the individual. If the individual follows the prescriber's directions, the 180 tablets will run out on the 30th day of taking the drugs.

420. Under 21 C.F.R. § 1306.12(a), "the refilling of a prescription for a controlled substance listed in Schedule II is prohibited." As a result, a pharmacy may dispense Schedule II controlled substances only pursuant to a *new* prescription written for the patient by a prescriber; it may not refill the earlier prescription. In certain circumstances, prescribers may, on the same date, issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance, but in doing so, the prescriber must provide "written instructions" on each prescription "indicating the earliest date on which a pharmacy may fill each prescription." 21 C.F.R. § 1306.12(b)(1).

421. In either case, when an individual requests to fill a prescription well before the previous supply has been exhausted or before the date that the prescriber has authorized the

prescription to be filled, it raises a significant red flag that the individual may have been abusing the drugs by taking more than the directed dose or that the individual has been diverting the drugs by selling them or otherwise distributing them to others.

422. Walmart has recognized that early refills could signal abuse. In POM 1311 (2015), Walmart recognized that a red flag is present when an "[i]ndividual routinely attempts to obtain an early refill on controlled substances." And in at least one communication, one of Walmart's corporate compliance managers, B.N., indicated that when there was a pattern of early refill requests, the pattern may "indicate that the prescription is being used in a manner other than how the … drug was prescribed."

423. Furthermore, Walmart had a policy, POM 1318 (2011), that directly addressed filling controlled substances early. It recognized that "[p]harmacists are … tasked by regulatory agencies with monitoring for signs of misuse or abuse of medications, in particular controlled substances," and indicated that Walmart's pharmacy management software, Connexus, alerted pharmacists when requests were made to fill prescriptions more than 72 hours ahead of the next permitted fill date of a controlled-substance prescription.

424. POM 1318 (2011) required the pharmacist to evaluate "the circumstances for the request and the patient's medication and previous refill history." Furthermore, POM 1318 (2011) stated that "[i]f the pharmacist overrides the warning and allows the refill to go through, whether the approval was obtained from the prescriber or in the exercise of the pharmacist's professional judgment, then Walmart, through the Connexus system, requires the pharmacist to document the reason for the override." The policy emphasized that "[i]t is important that pharmacists thoroughly and accurately document any details associated with their decisions to override early refill warnings, including any discussions with or approval from the prescriber."

425. Some of the prescriptions that Walmart pharmacists filled significantly early were written by problem prescribers that Walmart knew to be dangerous, including some of the prescribers described above. Moreover, many of these prescriptions showed additional red flags. Hundreds of them were paid for in cash, and hundreds more were dispensed to patients who were from a different state than the prescriber and/or pharmacy.

426. All told, from June 2013 forward, Walmart pharmacists filled thousands of these early prescriptions. These prescriptions were filled so early that they indicate that Walmart pharmacists would have known that substantially all of them were illegitimate.

D. Walmart filled many invalid prescriptions that were same or similar to other prescriptions Walmart pharmacists had previously identified as invalid for the same customer.

427. On numerous occasions, Walmart pharmacists filled a controlled-substance prescription that showed red flags, where the prescription was the same as or similar to a prescription that another Walmart pharmacist had previously recognized as invalid and had refused to fill for the same patient. In other words, even when one or more Walmart pharmacists had recognized that obvious red flags made a prescription invalid, another Walmart pharmacist filled the prescription or a similar one. Because the prescription had the same or similar red flags, the pharmacist who filled the prescription would have known that the prescription was invalid.

428. For example, on February 6, 2014, a pharmacist at Store 528 refused to fill prescriptions for lorazepam 1mg and oxycodone-acetaminophen 10/325mg because four different prescribers had been writing prescriptions for the same individual since December—a red flag that the individual was doctor shopping. The same pharmacy, however, filled those prescriptions for lorazepam 1mg and oxycodone-acetaminophen 10/325mg less than two weeks later, on February 17, 2014, and February 20, 2014.

429. On March 31, 2014, a pharmacist at Store 2459 in Sarasota, Florida, refused to fill an individual's prescriptions for methadone 10mg, Dilaudid 4mg, and Valium 10mg after concluding that the prescriptions were "inappropriate" because they were for high quantities, and "[p]er pain management guidelines methadone should not be taken with other opioids and benzodiazepines [due to] high risk of respiratory depression." The refusal-to-fill form also stated that the prescriptions were written by a physician who "frequently writes prescriptions for inappropriate/excessive naroctics [sic]." Nevertheless, the following day, a nearby store in Bradenton, Florida, Store 528, filled all three prescriptions, dispensing 30 tablets of diazepam 10mg (Valium), 100 tablets of hydromorphone 4mg (Dilaudid), and 150 tablets of methadone 10mg.

430. On April 4, 2014, a Walmart pharmacist at Store 5831 refused to fill a prescription for hydromorphone 8mg, recognizing that it was an "excessive dos[e]" of a short-acting opioid. Five days later, on April 9, 2014, a pharmacist at the same store filled that same prescription for 100 tablets of hydromorphone 8mg.

431. On April 12, 2014, a Walmart pharmacist at Store 2459 refused to fill a prescription for hydromorphone 4mg. The refusal-to-fill form from Store 2459 explained that the patient was taking a combination of drugs that "[p]er pain management guidelines … should not be taken together [due to] high risk of respiratory depression." The form also noted that "this physician frequently writes rx's for very large quantities of narcotics, and is an out of area physician." Two days later, a pharmacist at Store 1004 filled that prescription for 150 tablets of hydromorphone 4mg.

432. On April 14, 2014, a Walmart pharmacist at Store 3370 refused to fill a prescription for oxycodone 30mg because the individual was taking "a dangerous cocktail of

medications" and "the red flag and risk of over dose/dependence is high in this situation esp[ecially] in the addition of high streng[th] narcotics such as oxycodone." On April 28, 2014, a pharmacist at the same store filled that prescription.

433. On August 22, 2014, pharmacists at Walmart stores in Inverness and Lecanto, Florida, refused to fill an MS Contin 60mg prescription for a patient, with the pharmacists reporting in refusal-to-fill forms that the patient was "pharmacy shopping" and "has been to numerous pharmacies throughout Florida and has been to doctors from Brandon and Tampa." Just three days later, a Walmart pharmacist in Sebring, Florida, filled the same prescription.

434. On February 19, 2015, a Walmart pharmacist at Store 63 in Wagoner, Oklahoma, refused to fill a prescription for oxycodone 30mg for an individual because the "dosage and quantity [was] inap[p]ropriate for chronic pain management." The pharmacist pointed out that the individual also had prescriptions for "Soma, Adderall, Ambien, Tramadol, MS Contin, and Xanax," which in combination with the oxycodone, were "potentially dangerous," including possibly leading to "CNS [central nervous system] depression." Four days later, on February 23, 2015, a Walmart pharmacist in Coweta, Oklahoma, filled that prescription for 480 tablets of oxycodone 30mg.

435. From at least March 2016 to February 2017, Walmart pharmacists refused to fill prescriptions from a Wyoming prescriber, D.R.C., where the prescriptions presented obvious red flags—yet those same prescriptions were subsequently filled by other Walmart pharmacists.

436. In March 2016, a Walmart pharmacist refused to fill a hydrocodone-acetaminophen 10/325mg prescription written by D.R.C., citing numerous red flags. Despite these red flags, the pharmacy filled a prescription for the same medication for that individual in April, June, and August 2016 and filled a very similar prescription in July 2016.

437. On January 15, 2017, M.J., a Walmart director in the compliance unit, sent an email to several of her colleagues concerning the large "suspicious order" of oxycodone-acetaminophen 10/325mg placed by Store 4471 in Rawlins, Wyoming. The email noted that D.R.C. "[p]rescribes 66% of the Oxycodone/[acetaminophen] 10/325mg dispensed at this location," that "93% of the prescriptions" for one particular high-dose opioid were for very high quantities, and that "[s]everal of [D.R.C.'s] patients are being prescribed a 'cocktail' including an opioid, benzodiazepine and carisoprodol." At that Walmart pharmacy, a pharmacist technician and her pharmacy colleagues had a running joke that D.R.C.'s prescriptions were like fast-food orders: "I need a #1" referred to yet another D.R.C. prescription for hydrocodone.

438. Then, on January 23, 2017, Store 4471 refused a high-dose opioid prescription for a patient, explaining that D.R.C. "[w]rites prescriptions outside of scope of practice." Yet, later that same day, a different pharmacist at Store 4471 dispensed the same medication to the same patient, and the pharmacy did so again in February and March 2017.

439. Likewise, on February 21, 2017, a pharmacist at Store 4471 refused to fill an oxycodone-acetaminophen 10/325mg prescription written by D.R.C., explaining that D.R.C. wrote "prescriptions outside of scope of practice," and that there was evidence of "pharmacy shopping." Six days later, Store 4471 filled this prescription, despite the continued presence of these red flags.

440. In sum, in the various ways outlined in this Part, Walmart dispensed thousands upon thousands of prescriptions that its pharmacists would have known were invalid (or had a very high probability of being invalid), and, by filling these controlled-substance prescriptions despite the red flags, it also failed to comply with the usual course of professional pharmacist practice. Each time it did so, it violated its dispensing obligations under 21 C.F.R. § 1306.04(a)

and § 1306.06.

III. IN ITS ROLE AS A DISTRIBUTOR, WALMART VIOLATED THE CSA.

478. As alleged above, Walmart acted as a distributor of controlled substances, delivering large shipments to its pharmacies throughout the country. It also violated the CSA at least hundreds of thousands of times by failing to design and operate a system to detect and report suspicious orders to DEA.

479. The Attorney General, by regulation, has long required distributors to design and operate a system to detect suspicious orders of controlled substances, and to report those orders to DEA. *See* 21 C.F.R. § 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."). Suspicious orders "include" orders that are unusual in size, pattern, or frequency, but are not limited to only those three categories. *Id.*

480. As explained below, Walmart failed to comply with its obligation under 21 C.F.R. § 1301.74(b) and did not report at least hundreds of thousands of suspicious orders.

A. Walmart had access to a wealth of information and data such that it could readily have designed a system to adequately detect suspicious orders.

1. Walmart's self-distribution to its own pharmacies gave it extensive knowledge and data about dispensing patterns and orders.

481. From 2000 to approximately May 2018, Walmart self-distributed tens of millions of shipments of controlled substances to Walmart-branded and Sam's Club-branded pharmacies.

482. Walmart operated at least six distribution centers ("DCs") that distributed controlled substances to its pharmacies in the United States: Bentonville, Arkansas ("DC 6045"); Rogers, Arkansas ("DC 6001"); Tifton, Georgia ("DC 6013"); Crawfordsville, Indiana ("DC 6028"); Hanford, California ("DC 6032"); and Williamsport, Maryland ("DC 6046"). Of these

distribution centers, only Bentonville ("DC 6045") distributed Schedule II controlled substances.

483. Throughout the period from 2012 to 2018, Walmart was the largest self-distributor in the country for oxycodone, hydromorphone, and hydrocodone in terms of both dosage units and grams.

484. Because Walmart acted as its own distributor, it had access to extensive data and other information that independent distributors would not ordinarily have.

485. In particular, Walmart had a wealth of dispensing information that gave it the ability to investigate the circumstances underlying orders for controlled substances. Walmart had data about individuals who filled controlled-substance prescriptions at its pharmacies, the identities of the medical providers who were prescribing controlled substances for those individuals, and reports from its own pharmacists raising concerns.

486. Walmart had access to additional data and other information that it could have used to inform its decision as to whether an order was suspicious or not, including but not limited to:

a. instances in which a pharmacist had refused to fill prescriptions written by particular prescribers;

b. knowledge of "pill mill" prescribers whose patients filled prescriptions at Walmart pharmacies and the specific controlled substances that they often unlawfully prescribed to patients;

c. knowledge of Walmart's own pharmacists, pharmacy managers, and market directors;

d. the distance between prescribers, patients, and pharmacies;

e. information concerning patients who paid cash for controlled-substance

prescriptions;

f. drug diversion trends; and

g. previous DEA Form 106 (Theft and Loss) filings.

487. Walmart also had access to distribution-related data and other information, including but not limited to:

a. the number of bottles of controlled substances that each of its pharmacies had already ordered in any given week;

b. historical order quantities and patterns;

c. order and shipment history for orders that Walmart pharmacies placed with independent distributors (*e.g.*, McKesson Corporation and AmerisourceBergen Corporation), including reports warning when a pharmacy was nearing an independent distributor's threshold and information about instances when an independent distributor had refused to ship the order and reported the order to DEA as suspicious;

d. orders that had been previously flagged for its pharmacies;

e. analytics concerning each pharmacy's ratio of controlled-substance purchases to non-controlled-substance purchases;

f. previous suspicious-order reports for its pharmacies; and

g. prior and current suspicious order monitoring ("SOM") remediation plans, discussed below, for its pharmacies.

488. Walmart had the capability to use sophisticated data analytics to enhance and optimize its pharmacy operations. Walmart has emphasized that it relies on "big data" in its pharmacy operations to "enhance, customize and optimize the shopping experience" and "to

make Walmart pharmacies more efficient," namely by using the data to "help[] the pharmacy with staff scheduling and to reduce the amount of time it takes a prescription to be filled." https://corporate.walmart.com/newsroom/innovation/20170807/5-ways-walmart-uses-big-data-to-help-customers (last visited December 18, 2020).

489. Although Walmart had the ability to use all this data and other information to detect suspicious orders, it chose not to do so, as explained in detail in Part III.B below.

490. In addition to all of the data and other information to which Walmart had access, certain corporate employees had visibility into and control over Walmart's dispensing and distribution policies and practices.

491. In September 2015, Walmart created a "Health and Wellness Controlled Substance Advisory Panel" to oversee "the Health and Wellness Division's Controlled Substance Compliance Program ("Program"), which addresses compliance with state and federal laws, regulations and standards of conduct related to controlled substance dispensing and distribution."

492. One member of the Controlled Substance Advisory Panel, M.J., was, at times, responsible for developing both dispensing and distribution policies and practices.

493. Among her many responsibilities, M.J. reviewed "pill mill" prescribers as part of Walmart's "prescriber review committee," modified the refusal-to-fill policy and other policies related to dispensing, and handled dispensing data.

494. Additionally, M.J. oversaw Walmart's distribution compliance with respect to both high-level policy and day-to-day implementation of the SOM program. She was responsible for executing Walmart's SOM policies and "developed [a] strategy for a much more comprehensive program than was initially developed." And M.J. was one of two people charged with determining which orders placed by Walmart pharmacies were suspicious and therefore had

to be reported to DEA.

495. Although Walmart had access to all of this information and its corporate employees were aware of and had control over both the dispensing and distribution practices, Walmart failed to use this information and corporate knowledge in its SOM program.

2. Walmart had information on the millions of orders for controlled substances its pharmacies placed with—and received from—independent distributors.

496. In addition to the data and other information it had about its own distribution and dispensing, Walmart also had access to data and other information about the millions of orders shipped from independent distributors.

497. During the Distribution Violations Period, Walmart-branded pharmacies generally first placed all of their orders with Walmart's own distribution centers. Walmart-branded pharmacies generally received controlled substances from McKesson Corporation ("McKesson") when Walmart's distribution centers could not fulfill the order.

498. During the Distribution Violations Period, Walmart-branded pharmacies received millions of controlled-substance orders from McKesson.

499. During the Distribution Violations Period, Sam's Club-branded pharmacies used AmerisourceBergen Corporation ("AmerisourceBergen") as their primary distributor. Walmart's distribution centers served as a back-up distributor to Sam's Club-branded pharmacies.

500. During the Distribution Violations Period, Sam's Club-branded pharmacies received over a million controlled-substance orders from AmerisourceBergen.

501. Despite having information about how often and how much Walmart-branded pharmacies and Sam's Club-branded pharmacies ordered from independent distributors, Walmart did not account for these orders and shipments in its SOM program.

B. For years, Walmart knew of significant defects with its policies and procedures for detecting and reporting suspicious orders, but failed to fix them.

502. Both before and during the Distribution Violations Period, Walmart's SOM program contained significant defects that prevented Walmart from detecting and reporting at least hundreds of thousands of suspicious orders that its pharmacies placed with its distribution centers.

503. As explained below, numerous internal documents demonstrate that Walmart knew throughout this period of significant defects with its SOM program.

504. During the Distribution Violations Period, Walmart's SOM program—including the systems, policies, and procedures that Walmart employed to monitor suspicious orders—changed and went through multiple iterations.

505. However, these changes were not sufficient to fix the known defects and meet Walmart's legal obligation under 21 C.F.R. § 1301.74(b) to detect and report suspicious orders.

1. Prior to August 2015, Walmart had a rudimentary suspicious-order monitoring system that failed to adequately detect and report suspicious orders.

506. On or about December 27, 2007, DEA sent letters to all registered distributors of controlled substances, including Walmart, reminding them of their legal obligation under 21 C.F.R. § 1301.74(b) to detect and report suspicious orders to DEA.

507. In the December 27, 2007 letter, DEA advised distributors that failing to comply with their obligations could lead to great harm: "[A]ll registrants—manufacturers, distributors, pharmacies, and practitioners—share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

508. Nevertheless, prior to November 2010, Walmart had no written policies or procedures related to the identification or reporting of suspicious orders.

509. In November 2010, Walmart adopted Pharmacy Manual 21-402 ("Controlled Substance Monitoring").

510. This policy simply required certain Walmart employees to review a monthly report, known as a "control drug stock exception report," after the controlled substances had been shipped to the pharmacies and identify any controlled substances that constituted more than 3.99% of a pharmacy's total controlled and non-controlled-substance purchases during the prior month.

511. Under Pharmacy Manual 21-402 (November 2010), Walmart failed to detect many unusual orders. First, the monthly reports did not identify specific controlled-substance orders that were unusually large. Instead, the reports aggregated all shipments of particular controlled substances and then compared those aggregated totals to see if they exceeded 3.99% of a pharmacy's total shipments that month. As a result, many unusually large orders were not flagged because they were subsumed in the aggregated totals. Second, the policy did not require Walmart to flag any orders that were otherwise suspicious (*e.g.*, exhibiting an unusual frequency or unusual pattern).

512. Pharmacy Manual 21-402 (November 2010) did not describe these aggregated totals as "suspicious orders" or even state that Walmart was required to detect and report suspicious orders to DEA.

513. By mid-2014, Walmart officials recognized that Walmart was at risk of enforcement from DEA because it was not detecting and reporting suspicious orders as required by 21 C.F.R. § 1301.74(b). In an attachment to a June 12, 2014 email sent by M.J. (then

Director of Compliance), Walmart considered modifying its SOM system "to help Walmart avoid DEA enforcement as a result of non-compliance with 21 CFR 1301.74(b)."

514. In that same June 12, 2014 email, Walmart attached a risk assessment in which it observed that its system for monitoring suspicious orders was an "existing risk" and "emerging risk" for which it had "no processes in place." Walmart's own assessment was that the risk that its pharmacies would place suspicious orders with its own distribution centers was "likely," the second-highest of five levels on Walmart's scale of likelihood of risks.

515. In July 2014, Walmart revised Pharmacy Manual 21-402 and titled the revised policy "Evaluating Orders of Interest and Suspicious Order Reporting."

516. Unlike the 2010 version of the policy, Pharmacy Manual 21-402 (July 2014) instructed compliance unit personnel to evaluate individual orders as they were placed—rather than monthly aggregated totals after Walmart's distribution centers had already shipped the controlled substances—and report any suspicious orders to DEA.

517. Pharmacy Manual 21-402 (July 2014) called for Walmart first to identify "orders of interest" from among all controlled-substance orders, and then to investigate those "orders of interest" to determine whether they were indeed "suspicious orders" subject to reporting to DEA. As detailed below, however, both steps of this system failed. The criteria Walmart adopted for flagging "orders of interest" in the first instance were plainly inadequate, allowing many suspicious orders to evade any scrutiny. And Walmart routinely failed to investigate orders that were flagged as "orders of interest" to ascertain whether they were suspicious, prioritizing expeditious distribution of controlled substances to meet its pharmacies' and pharmacists' demands over compliance with DEA regulations.

518. As a result of these defects, even under the revised SOM policy, Walmart

reported only a miniscule percentage of its pharmacies' suspicious orders.

a. Walmart failed to detect and report orders of unusual frequency or pattern.

519. Pharmacy Manual 21-402 (July 2014) stated that Walmart must evaluate orders with "[u]nusual characteristics," which it defined to include orders showing "unusual size," "unusual frequency," and "unusual pattern."

520. Despite the requirements in 21 C.F.R. § 1301.74(b) and in Walmart's own SOM policy to detect and report orders showing "unusual frequency" and "unusual pattern," Walmart's SOM system focused exclusively on the size of orders. It contained no processes to detect or report orders with unusual frequency or unusual pattern.

521. During the Distribution Violations Period, most of Walmart's six distribution centers used a system called Reddwerks as their order fulfillment system. Reddwerks tracked orders placed by Walmart pharmacies, as well as shipments from Walmart distribution centers back to the pharmacies in fulfillment of those orders.

522. Although the Reddwerks system was not designed for monitoring suspicious orders, Walmart used it for that purpose. Specifically, Walmart used Reddwerks to set "order alerts"—sometimes known as "thresholds"—that would flag only orders over a certain quantity.

523. Walmart had an opportunity to design a system that would have detected unusual ordering patterns. As early as February 2014, Mu Sigma, an outside consultant that advised Walmart about the development of its SOM program, informed Walmart that it could revise that program to detect Walmart pharmacies' unusual ordering patterns and combinations, which could indicate that a particular Walmart pharmacy was dispensing dangerous drug "cocktails."

524. Despite this offer from Mu Sigma, Walmart did not revise its SOM program in that way or any other way to detect unusual, dangerous patterns during the Distribution

Violations Period.

525. Walmart knew that its SOM system was deficient in that it ignored pattern and frequency, in violation of the law. In an internal presentation from October 2014, just a few months after the July 2014 SOM policy had been put in place, Walmart recognized that Reddwerks "[f]lags only identify 'unusual size.'" That deficiency remained uncorrected for years.

526. Because Walmart's system was not designed to flag orders for unusual frequency and unusual pattern, Walmart did not report any of these orders to DEA, in violation of the law.

b. Walmart failed to adequately detect and report unusually large orders.

527. Despite Walmart's sole focus on order size, its monitoring still failed to detect significant numbers of orders of "unusual size."

528. There were several different flaws in Walmart's approach to monitoring the size of orders, as explained below.

i. In setting order-size thresholds and limits, Walmart disregarded the differences among its pharmacies and the differences among controlled substances.

529. Sometime prior to the adoption of Pharmacy Manual 21-402 in July 2014, Walmart's SOM program began using weekly size "thresholds" and "hard limits" for the quantity of controlled substances that each of its pharmacies could order from the six Walmart distribution centers.

530. An order that hit a "threshold" was supposed to trigger a temporary "hold" of that order for further evaluation.

531. A "hard limit" nominally served as the maximum amount that a pharmacy could order of a particular drug, but as explained below, Walmart sometimes ignored its own hard

limits, allowing its pharmacies to order and receive quantities greater than the hard limit.

532. The thresholds and hard limits ignored significant differences between pharmacies. Walmart knew that its pharmacies varied significantly in many respects. For instance, some served sparsely populated rural communities, while others served suburban or urban communities with larger populations. Likewise, depending on location, Walmart pharmacies might face differing levels of competition from other retail chain pharmacies or independent pharmacies. Customer characteristics also differed in material ways, such as age and diagnoses, which affected the types and amounts of controlled substances each pharmacy needed to stock and dispense to meet customer demand.

533. Despite its knowledge of these variations among pharmacies, Walmart applied the same numeric thresholds to each of its pharmacies and did not tailor its order-size thresholds. Regardless of the attributes of the pharmacy placing an order, Walmart's SOM system uniformly flagged the following weekly order totals:

a. Schedule II controlled substances that exceeded 20 bottles,

b. Schedule III-V controlled substances that exceeded 50 bottles, and

c. 30% above four-week average (if 11 bottles or greater).

534. In a document titled "Overview of SOM Project Progress," which was attached to a November 23, 2014 email from a senior manager of logistics to other compliance unit personnel, Walmart acknowledged that thresholds for its pharmacies were set "regardless of store history."

535. In addition, Walmart had no supporting rationale for its decision to set a 50-bottle threshold for Schedule III, IV, and V controlled substances. The "Overview of SOM Project Progress" stated that Walmart lacked any documentation showing why 50 bottles had been

selected as a threshold for certain controlled substances.

536. This arbitrary, one-one-size-fits-all threshold for all Schedule III, IV, and V controlled substances meant that a pharmacy could order the same amount—up to 50 bottles—of a highly addictive Schedule III narcotic as it could order of a Schedule V controlled substance with a lower potential for abuse.

537. As a result of Walmart's one-size-fits-all approach in setting thresholds and hard limits, Walmart failed to detect and report many unusually large orders.

ii. Walmart routinely shipped, and did not report, orders exceeding its hard limit for oxycodone 30mg.

538. Starting in or about July 2012, Walmart implemented a "hard limit" of 20 bottles of oxycodone 30mg per week, per pharmacy.

539. Oxycodone 30mg was the only controlled substance and only dosage strength for which Walmart imposed a "hard limit" on the number of bottles its pharmacies could order each week.

540. Despite this singular focus on this one drug formulation, Walmart frequently disregarded its own 20-bottle "hard limit" for oxycodone 30mg, a highly addictive Schedule II controlled substance.

541. Between June 2013 and July 2015, on at least 216 separate occasions, Walmart shipped to its pharmacies more than 20 bottles of oxycodone 30mg in one week.

542. This problem was concentrated in a handful of pharmacies. Approximately half of the instances where Walmart disregarded its own hard limit of 20 bottles of oxycodone 30mg went to only six pharmacies: Store 5350 in Salt Lake City, Utah; Store 1560 in Las Vegas, Nevada; Store 5697 in Milwaukee, Wisconsin; Store 2708 in Temecula, California; Store 130 in Muskogee, Oklahoma; and Store 5047 in Audubon, New Jersey.

543. For example, during a 12-week period in 2015, Store 130 in Muskogee, Oklahoma, received more than 20 bottles of oxycodone 30mg in 11 of those weeks, for a total of 248 bottles. These suspiciously large orders of oxycodone 30mg and Walmart's failure to report them to DEA are particularly egregious because, as set forth above, Walmart also knew that S.L. was operating a pill-mill practice in Muskogee and his patients were using Store 130 to fill unlawful prescriptions. Walmart pharmacists at Store 130 had reported to Walmart compliance personnel that "there is a significant drug abuse problem in town" and that "many" of S.L.'s patients "don't take [their prescribed] meds, they sell them – sometimes before they even leave the store."

544. By way of another example, over a 14-week period in 2014, Walmart repeatedly shipped well over 20 bottles of oxycodone 30mg to Store 5350 in Salt Lake City, Utah. Walmart ultimately shipped a total of 399 bottles to this pharmacy over these 14 weeks. Moreover, during the broader time period of June 2013 through July 2015, on 41 separate occasions, Walmart sent weekly shipments totaling more than 20 bottles of oxycodone 30mg to Store 5350.

545. Despite repeatedly violating its own hard limit, Walmart did not report to DEA as suspicious any of the orders resulting in the shipments identified above.

iii. Walmart's size thresholds were based on the number of bottles—rather than the number of dosage units in those bottles—which made those thresholds ineffective at detecting unusually large orders.

546. Prior to August 2015, Walmart's size thresholds were based on the number of bottles, rather than on the number of dosage units included in each bottle.

547. In the "Overview of SOM Project Progress," Walmart recognized this deficiency, noting that "[m]onitoring level = 50 bottles (regardless of store history, *bottle size,* etc) or order amount >30% over rolling 4 week average." (Emphasis added.)

548. Because of this flaw, pharmacies could evade the bottle-based thresholds, obtaining more dosage units of controlled substances without scrutiny by ordering bottles containing more pills.

549. For example, in two shipments on December 12 and 13, 2013, Store 7259 in Georgetown, Kentucky, received a total of 10 bottles of oxycodone hydrochloride-acetaminophen 5/325mg, each containing 500 pills. Store 7259 thus received 5,000 dosage units in one week. Store 7259 could have obtained the same number of dosage units by ordering bottles containing only 100 pills per bottle, but then it would have ordered 50 bottles and exceeded the 20-bottle threshold. Instead, Store 7259 was able to receive 2.5 times as many pills while evading scrutiny—and potential reporting to DEA as a suspicious order—because it stayed below the 20-bottle threshold simply by ordering a larger bottle size.

550. In another instance, on February 26 and 27, 2014, Store 2156 in Middle Island, New York, received a total of nine bottles of oxycodone hydrochloride-acetaminophen 5/325mg, each containing 500 pills. Store 2156 thus received 4,500 dosage units in one week. If Store 2156 had ordered bottles containing only 100 pills per bottle, the pharmacy would have had to order 45 bottles to obtain the equivalent dosage units, which would have exceeded the 20-bottle threshold for evaluation of Schedule II controlled-substance orders. Instead, Store 2156 was able to receive over two times as many pills while evading scrutiny—and potential reporting to DEA as a suspicious order—because it stayed below the 20-bottle threshold simply by ordering a larger bottle size.

551. Throughout this period, Walmart knew that setting thresholds based on bottle quantity rather than dosage-unit quantity presented a potential loophole for pharmacies to order excessive amounts of controlled substances.

552. In a memorandum drafted on or about October 11, 2013, E.O., the General Manager of DC 6046 in Williamsport, Maryland, pointed out that "several control … items have changed from a 100 count bottle to a 1000 count bottle," such that a pharmacy that had previously ordered 20 bottles of a controlled substance for a total of 2,000 dosage units was now able to order 20 bottles of that same controlled substance for a total of 20,000 dosage units. E.O. concluded that "[t]he system now should flag pills verses [sic] bottles."

553. Although Walmart recognized as early as October 2013 that relying on order-size thresholds based on the number of bottles presented problems, Walmart delayed fixing this problem and did not implement order-size thresholds based on the number of dosage units until at least August 2015.

iv. Walmart's size thresholds were based on specific National Drug Code numbers—rather than drug type and strength—which made them ineffective at detecting unusually large orders.

554. Another flaw in Walmart's size thresholds was that Walmart's SOM program did not aggregate and flag multiple orders placed by a pharmacy for the same drug and strength, if those orders were for products that had different National Drug Codes because they were made by different manufacturers. A National Drug Code ("NDC") is a unique, three-segment number which serves as a universal product identifier for drugs.

555. For example, in 2014, DC 6045 shipped Store 5350 in Salt Lake City, Utah, several orders of oxycodone 30mg that were unusual when aggregated. Over the course of one week from November 25-28, 2014, Store 5350 received 16 bottles of oxycodone 30mg (NDC 10702000901) and 19 bottles of oxycodone 30mg (NDC 228287911), but neither weekly shipment total—based on NDC alone—was flagged as exceeding 20 bottles. Each order exceeding the weekly hard limit of 20 bottles of oxycodone 30mg should have been flagged and

reported to DEA as suspicious, but Store 5350 evaded the 20-bottle hard limit because the NDCs differed, allowing Store 5350 to receive 35 bottles of oxycodone 30mg in one week, almost twice the hard limit because of this loophole.

556. In another example, Store 2837 in Las Vegas, Nevada, received shipments of 12 bottles of oxycodone 30mg (NDC 10702000901) and 18 bottles of oxycodone 30mg (NDC 228287911) from DC 6045 on January 8, 2014. This weekly total of 30 bottles of oxycodone 30mg exceeded the 20-bottle hard limit, but was not flagged and reported to DEA as suspicious because Walmart failed to monitor for differing NDCs for the same drug strength.

557. Walmart's failure to close this NDC loophole enabled the oxycodone 30mg hard limit of 20 bottles to be exceeded at least 146 times between June 26, 2013, and July 31, 2015.

558. This problem of not evaluating the orders in the aggregate was not limited to orders of oxycodone 30mg, but extended to other Schedule II controlled substances. Because Walmart did not monitor Schedule II orders of the same drug and strength with different NDCs, Walmart's SOM system failed to flag at least 1,500 weekly shipments of other Schedule II controlled substances with a combined weekly total above 20 bottles for further evaluation.

v. When Walmart flagged orders of unusual size, it often "cut" or reduced the size of the orders, but failed to report them to DEA.

559. Walmart also avoided reporting suspicious orders by "cutting," *i.e.*, reducing the size of orders that would otherwise raise concerns, down to a size Walmart considered acceptable. Specifically, when Walmart received an order from one of its pharmacies above the threshold of 20 bottles for a Schedule II controlled substance, or 50 bottles for a Schedule III, IV or V controlled substance, Walmart often "cut" that order down to 20 or 50 bottles.

560. For instance, on October 16, 2014, J.A., Operations Manager at DC 6045, circulated a report to other Walmart compliance personnel, including to M.J., showing several

orders greater than 50 bottles that had been "cut" down to 50 bottles and shipped out to pharmacies the prior day:

Date	Store	NDC	Description	Item Pack Quantity	Ordered	Sent
10/15/2014	1783	603388721	HYD/BIT/ACET 10/325	100	63	50
10/15/2014	5133	406012501	HYDRO/APAP 10/325MG	100	82	50
10/15/2014	1575	406012501	HYDRO/APAP 10/325MG	100	76	50
10/15/2014	1951	406012501	HYDRO/APAP 10/325MG	100	63	50

561. Walmart did not send DEA a suspicious-order report for any of the cut orders listed above.

562. After Walmart set the 20-bottle hard limit for oxycodone 30mg orders in or about July 2012, the company's policy was that oxycodone 30mg orders exceeding the 20-bottle weekly limit were to be flagged and "cut" down so that the pharmacy would receive no more than 20 bottles.

563. In an October 14, 2013 email, J.A. stated that DC 6045—which was the only Walmart distribution center that distributed oxycodone 30mg—had a "standing" cut for oxycodone 30mg and that "[a]ny order over 20 bottles of this item is cut back to 20 bottles."

564. Although Walmart cut these orders and shipped the reduced (but still substantial) quantities of controlled substances to its pharmacies, Walmart did not report these unusually large orders to DEA.

565. Walmart's practice of cutting these unusually large orders and shipping the reduced portion without reporting the original large orders to DEA disguised the large quantities that its pharmacies repeatedly ordered.

566. Worse still, Walmart knew that its practice of shipping "cut" orders violated DEA regulations.

567. For example, in a February 2015 meeting, DEA diversion investigators informed

Walmart that Walmart's practice of receiving an order, reducing the quantity of the order, and shipping that reduced quantity without reporting the order as suspicious to DEA violated 21 C.F.R. § 1301.74(b).

568. Despite this knowledge, Walmart continued to unlawfully cut and ship orders without reporting them to DEA through at least November 29, 2017.

vi. Walmart ignored shipments of controlled substances that its pharmacies were also receiving from independent distributors.

569. Walmart recognized and knew that the SOM program had an additional, critical shortcoming: Walmart-branded pharmacies and Sam's Club-branded pharmacies ordered and received at least hundreds of thousands of shipments of controlled substances from McKesson and AmerisourceBergen, respectively, but Walmart did not factor in these shipments from independent distributors when considering whether the pharmacies had exceeded order-size thresholds and hard limits.

570. McKesson, as a back-up supplier for Walmart-branded pharmacies, shipped at least hundreds of thousands of controlled-substance orders to Walmart-branded pharmacies from June 2013 through July 2015.

571. AmerisourceBergen was the primary distributor for Sam's Club-branded pharmacies, and Walmart was a back-up supplier. As the primary distributor, AmerisourceBergen shipped at least hundreds of thousands of controlled-substance orders to Sam's Club-branded pharmacies from June 2013 through July 2015.

572. For Schedule II controlled substances, Walmart required its pharmacies to place all orders through DC 6045—even orders that would ultimately be fulfilled by independent distributors when DC 6045 was out of stock or did not carry a particular Schedule II controlled substance.

573. Schedule III, IV, and V controlled substances were handled differently. For Schedule III, IV, and V controlled substances, sometimes pharmacies placed orders directly with independent distributors rather than channeling all orders through a Walmart distribution center first.

574. There were two problems with how Walmart's SOM system accounted for orders from independent distributors.

575. First, even when Walmart knew that the independent distributor would ultimately fulfill an order, and thereby push the pharmacy's weekly order total above Walmart's order-size thresholds (*e.g.*, 20 bottles, 50 bottles, or 30% above the four-week average), Walmart passed the order along to the independent distributor for fulfillment without evaluating whether the order was suspicious. Had Walmart been abiding by its legal obligation to detect and report suspicious orders, Walmart would have reported that order to DEA.

576. Because of this system failure and other failures to monitor orders with independent distributors, between June 2013 and July 2015, Walmart unlawfully failed to detect and report to DEA thousands of its pharmacies' unusually large orders.

577. Second, Walmart's compliance personnel did not even know of some orders fulfilled by independent distributors because Walmart pharmacies could bypass Walmart distribution centers altogether and order directly from independent distributors. Walmart's SOM system did not identify these orders, leaving Walmart's compliance unit in the dark about the quantity of Schedule III, IV, and V controlled substances ordered from independent distributors. Because Walmart did not identify these orders, it of course did not evaluate them.

578. Walmart recognized that its SOM system had this blind spot. In an October 2014 internal presentation assessing the efficacy of its SOM system, Walmart noted that "McKesson

orders are not considered in evaluation." Likewise, the "Overview of SOM Project Progress" attached to a November 23, 2014 email stated that Walmart had "[n]o process for including McKesson orders in evaluation."

vii. Walmart attributed unusually large orders to "errors" to avoid reporting them as suspicious orders.

579. Walmart made up other reasons for not reporting unusually large orders to DEA. In particular, Walmart began classifying unusually large orders as "errors" in order to justify rejecting the order or reducing the size of the order, even when there was no basis for thinking the pharmacies had intended to order a smaller quantity.

580. In an email dated August 27, 2014, K.S., Senior Manager for Logistics, advised that "'[c]utting' an order should *only* be an option if the order is an error (eg store intended to order 10 bottles, ordered 100)." (Emphasis added.)

581. Although Walmart was aware that it should limit "cutting" orders to true "errors," J.A., the operations manager for DC 6045, stretched the meaning of "error" so broadly that it would conceal all sorts of suspicious activity.

582. In an internal email dated November 5, 2014, concerning the use of "error" as a reason code for cutting orders, J.A. wrote: "Many things could be considered an 'error' other than just mis-keying an order. Such as, due to the change of Hydro to a CII some pharmacist[s] feel the need to stock up. The company feels 50 bottles is enough and pharmacist shouldn't stock up, thus an error in decision making. And many other reasons not confined to mis-keying." (On October 6, 2014, hydrocodone was reclassified from a Schedule III controlled substance to a Schedule II controlled substance, which reflected DEA's concern regarding the abuse and diversion potential of hydrocodone.)

583. Walmart thus expanded its definition of "error" beyond its pharmacies'

unintentional mistakes to include their deliberate placement of unusually large orders. This overly expansive definition of "error" caused Walmart to fail to report suspicious orders to DEA.

c. Walmart ignored specific signs of diversion from its own pharmacies.

584. In addition to altogether failing to detect orders of unusual frequency or pattern and failing to adequately detect orders of unusual size, Walmart's SOM program also ignored signs that diversion was occurring at certain pharmacies.

585. As noted above, 21 C.F.R. § 1301.74(b) defines suspicious orders as including orders that are suspicious for reasons other than unusual size, unusual frequency, or deviating from the normal pattern, but does not limit the definition to these three categories.

586. Nevertheless, in addition to ignoring the three categories listed in the regulation, Walmart's compliance unit ignored other warning signs that orders placed by certain pharmacies were suspicious. These signs included concerns expressed by pharmacists to compliance personnel about prescriptions written by "pill mill" prescribers and illegal diversion occurring inside Walmart stores.

587. For instance, in a series of emails, the pharmacy manager of Store 147 in Denison, Texas, warned Walmart's compliance unit about a Texas prescriber, H.D., who is discussed above. Despite these concerns, Walmart took no action to limit the shipment of controlled substances to Store 147, which routinely filled prescriptions issued by H.D., and failed to notify DEA of suspicious orders from those stores.

588. Likewise, Walmart received numerous warnings regarding North Carolina prescriber S.K., as discussed above. Over a period of two years from July 2013 to July 2015, Walmart's compliance unit received more than 70 warnings from pharmacy managers and pharmacists at Walmart pharmacies in North Carolina about S.K., including warnings about his

practice of prescribing high volumes of Schedule II controlled substances.

589. Walmart pharmacists submitted more than 70 refusal-to-fill forms that warned that S.K.'s prescriptions had no legitimate medical purpose and raised numerous and repeated red flags related to S.K., his patients, and the prescriptions he wrote. For example, one refusal-to-fill form by a pharmacist from Store 3825 in Havelock, North Carolina, explained that S.K. "only writes for large qty [sic] of narcotic medications." The next day, another pharmacist at Store 3864 in Jacksonville, North Carolina, submitted a refusal-to-fill form about another one of S.K.'s opioid prescriptions and warned that the prescription was "written by a doctor that is known to give large quantities of c2 [*i.e.*, Schedule II] prescriptions and no other ones." (Emphasis omitted.) Nine months later, a pharmacist at Store 7238 in Grantsboro, North Carolina, reported in a refusal-to-fill form that S.K.'s patient "appeared intoxicated (slurred speech [sic], unstable, glossy eyes)" and that the "prescription [was] written for [a] large quantity." (Emphasis omitted.)

590. Despite knowing about all of these warnings of diversion from its own pharmacists, Walmart took no action to limit the shipment of controlled substances to pharmacies routinely filling prescriptions issued by S.K. and did not report any suspicious orders for Stores 3825, 3864, or 7238 to DEA.

591. As another example, Walmart's compliance unit had ample warning that Z.B., who is discussed above, was a "pill mill" doctor whose patients traveled great distances to visit his pain clinic in Tampa, Florida, and/or to fill his prescriptions at Walmart pharmacies located within a large radius from his pain clinic.

592. Fifty-five miles from Tampa, Store 959 in Bushnell, Florida, was the largest Walmart dispenser of Z.B.'s prescriptions. Pharmacists at that store submitted several refusal-to-

fill forms relating to Z.B., and one of the pharmacists noted, among other things, "prescriber questionable."

593. In June 2016, M.J., Director of Controlled Substances, notified Walmart's Regional Health and Wellness Director for Florida, Alabama, Mississippi, and Georgia that Z.B. was one of the top three prescribers for oxycodone 30mg at Store 5654 in Tampa, that 75 percent of Z.B.'s prescriptions for oxycodone 30mg were for quantities of 120 dosage units or greater, and that the top-three drugs prescribed by Z.B. were oxycodone 30mg, hydromorphone 8mg, and methadone 10mg.

594. A month-and-a-half later, in mid-August 2016, M.J. told B.N., a director in the compliance unit, and other Walmart compliance personnel that Z.B. was the number-one prescriber of oxycodone 30mg at Store 5964 in Tampa, accounting for 14 percent of all such prescriptions dispensed by Store 5964.

595. Despite all of these warning signs of diversion, Walmart took no action to limit the shipment of controlled substances to pharmacies routinely filling prescriptions issued by Z.B. and did not report any suspicious orders for Stores 959, 5654, or 5964 to DEA.

d. Walmart failed to adequately staff and train its compliance personnel, and shipped flagged orders before compliance personnel could examine them.

596. During the Distribution Violations Period, Walmart was the largest private employer in the United States. For the fiscal year ending January 2015, Walmart employed 2.2 million associates worldwide, with approximately 1.4 million domestic employees.

597. Yet during this period, Walmart failed to devote sufficient personnel to operate its SOM program. Instead, Walmart was woefully understaffed for reviewing flagged orders from its 5,000 pharmacies and determining which of those orders were suspicious, and therefore, had to be reported to DEA.

598. For at least part of the time from June 2013 through July 2015, compliance personnel working in Walmart's Home Office were not involved in detecting suspicious orders. K.S., a Senior Manager for Logistics, has stated that "any decisions that needed to be made were being left to the distribution center…."

599. Walmart recognized this arrangement as inadequate and, in the "Overview of SOM Project Progress" attached to a November 23, 2014 email, listed several problems associated with Walmart's failure to involve Home Office compliance personnel in monitoring suspicious orders, including:

a. "Inconsistent application of monitoring standards by associate across DC facilities";

b. "No consistent training for associates";

c. "No dedicated [Home Office] resource"; and

d. "SOM policy only included DC associate responsibilities – no [Home Office] involvement or cross-functional collaboration."

600. Walmart's distribution centers were not staffed with enough personnel to evaluate all flagged orders.

601. Of particular concern was that Walmart failed to devote sufficient staff to monitoring orders of Schedule II controlled substances, which were the most dangerous controlled substances that Walmart distributed. All Schedule II controlled substances distributed by Walmart were distributed via DC 6045 in Bentonville, Arkansas. DC 6045 filled Schedule II orders itself, and it served as the intermediary between Walmart's pharmacies and the independent distributors when DC 6045 could not fill Schedule II orders on its own. At one point, there were only three employees at DC 6045 to review and evaluate hundreds of orders for

Schedule II controlled substances that Walmart's own thresholds had flagged each day (and many more after hydrocodone was reclassified as a Schedule II drug effective October 6, 2014).

602. Walmart also did not allow its staff adequate time to examine flagged orders for Schedule II drugs placed with DC 6045. Although Walmart policy called for a temporary "hold" to evaluate orders that had tripped the company's thresholds, that "hold" was often overridden in favor of expeditious shipping to satisfy its pharmacies. At least at one point in time, if DC 6045 flagged orders exceeding 50 bottles but did not receive an instruction by 3 p.m. that same day as to whether the order was suspicious or appropriate for shipment, the distribution center shipped the unusually large order without notifying DEA.

603. At other distribution centers, Walmart similarly failed to provide its staff with the ability to evaluate the stream of orders from its pharmacies.

604. For example, DC 6046 in Williamsport, Maryland, refused to devote adequate resources and personnel to properly evaluating orders that Walmart's SOM system had flagged for evaluation. As a result, it chose not to review every flagged order. In a memorandum circulated on or about October 11, 2013, E.O., an operations manager at DC 6046, stated that there were "too many orders to review each line [of Reddwerks orders alerts] in detail."

605. A year later, the problem had not been fixed. An internal presentation from October 2014 recognized that "[a]ll flags must be cleared before production on any items can begin, *so there is limited time for evaluation*." (Emphasis added.)

606. Walmart also failed to provide consistent, adequate training to the employees responsible for suspicious-order monitoring functions.

607. First, Walmart assigned SOM functions such as detecting, rejecting, and reporting suspicious orders, approving orders in excess of a threshold, and cutting orders to or below

thresholds, to distribution center personnel who Walmart knew had limited or no prior experience with suspicious-order monitoring or even with regulatory compliance of any kind.

608. Second, Walmart failed to provide these employees with training specific to monitoring suspicious orders of controlled substances, including appropriate training regarding drug diversion trends and the prescription drug abuse epidemic. Walmart provided its staff with no training program, training materials, or written policies, procedures, or criteria specific to suspicious-order monitoring.

609. For example, J.A., the operations manager at DC 6045, possessed neither adequate experience nor training when he was charged with determining which Schedule II orders were suspicious. Walmart provided J.A. with no formal training and no written policies or procedures specific to suspicious-order monitoring. Instead, J.A. relied on on-the-job experience working with Schedule II drugs and "just looking at orders and just, you know, if something looked unusual, then that's what I looked at."

e. Walmart routinely failed to investigate flagged "orders of interest" and report any orders to DEA that Walmart was unable to clear.

610. During this time period, Walmart set the following thresholds to flag unusually large orders for investigation: more than 20 bottles for Schedule II controlled substances, more than 50 bottles for Schedule III, IV, and V controlled substances, and order amounts that were 30% above the four-week average.

611. Pharmacy Manual 21-402 (July 2014) required Walmart to hold and evaluate all orders flagged by its SOM system. The manual referred to such orders as "orders of interest" and noted specifically that they "warrant[ed] follow-up evaluation to determine whether … [they are] suspicious."

612. Consistent with the manual, K.S., a Senior Manager for Logistics, stated in an

August 27, 2014 email: "Our obligation is to monitor all orders, *investigate 'orders of interest' (potentially 'suspicious' orders), hold any 'order of interest' until/unless the order is investigated and cleared* and report any 'suspicious' orders to DEA." (Emphasis added.)

613. Despite this clear policy, Walmart routinely failed to investigate thousands of flagged orders.

614. For example, Walmart generated an internal report referred to as an "Over 20 report," which flagged all orders for Schedule II controlled substances that were greater than 20 bottles. Walmart referred to orders of more than 20 bottles of Schedule II controlled substances as "orders of interest" that warranted additional evaluation.

615. But in many cases, no Walmart personnel at any level completed any investigation of these "Over 20" orders of powerful Schedule II controlled substances.

616. Walmart did not use these Over 20 reports to detect suspicious orders and report them to DEA. Walmart has admitted that it shipped all Schedule II orders of between 21 and 50 bottles that its pharmacies placed—without conducting any meaningful investigation into those orders, and sometimes conducting no investigation at all.

617. From June 26, 2013, to July 31, 2015, Walmart shipped its pharmacies at least 66,000 Schedule II orders in which the weekly totals ranged from 21 to 50 bottles.

618. In addition, one of Walmart's distribution centers—DC 6001 in Rogers, Arkansas—routinely shipped orders it had flagged for review, without reviewing them.

619. For at least part of the Distribution Violations Period, DC 6001 did not use Reddwerks to identify suspicious orders but, instead, used a system called KNAPP.

620. KNAPP was an order fulfillment system, but it had very limited ability to detect unusual orders of controlled substances.

621. Under the KNAPP system, once an order was "flagged" by DC 6001 for further evaluation, the system could not "hold" that specific order while the order was scrutinized to determine if it was suspicious or not. Instead, due to limitations of the KNAPP system, if DC 6001 held a pharmacy's order for further evaluation, then all the other orders would also be held and not shipped.

622. In an email dated August 25, 2014, K.S., a Senior Manager for Logistics, noted that some Walmart employees were "uncomfortable with our inability to find a systemic or manual solution that would allow us to 'hold' orders pending evaluation." The email further stated that Practice Compliance "would prefer to move all of the Control drug business out of 6001 and to McKesson until the KNAPP solution is in place."

623. However, Walmart did not move its controlled-substance business from DC 6001 to McKesson, instead continuing to use KNAPP and operate a system that Walmart knew was flawed.

624. The "Overview of SOM Project Progress" listed specific deficiencies with KNAPP, noting that:

a. "[DC] 6001 had very limited ability to monitor orders – KNAPP does not include monitoring functionality"; and

b. "System (Reddwerks or KNAPP) did not allow alerted orders to be 'held' pending evaluation."

625. Because KNAPP did not enable Walmart to hold an order while evaluating that order, Walmart routinely shipped suspicious orders without evaluating them and without reporting them to DEA. In fact, during this time, DC 6001 reported no suspicious orders at all.

f. Walmart often failed to document its evaluation of flagged orders, which deprived Walmart of crucial information needed to assess subsequent orders.

626. Walmart's SOM policy required compliance personnel to evaluate flagged orders and then document those evaluations.

627. Under Pharmacy Manual 21-402 (July 2014), Walmart's evaluations of flagged orders were to be documented using the "Order of Interest Evaluation Form." The policy stated that "[a]ll documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years."

628. Likewise, Walmart's Practice Compliance division adopted a policy in January 2015, referred to as "Controlled Substances Suspicious Order Monitoring," which required Walmart to "document the final conclusion of the evaluation" and "retain documentation of any reports made to the DEA and state agencies."

629. However, prior to 2015, Walmart had no system or process in place to document and retain this information.

630. Walmart recognized this flaw with its SOM system. The October 2014 internal presentation noted that there was "[n]o defined process for tracking why DC cuts or clears specific orders." Likewise, the "Overview of SOM Project Progress" acknowledged that Walmart had "[n]o process for documenting order evaluations or reporting decisions."

631. In those instances when Walmart conducted some due diligence on flagged orders, it often did not record the factual information it may have gathered about the order or the conclusion it made as to whether or not the order was suspicious.

632. For example, from June 26, 2013, through July 31, 2015, Walmart shipped tens of thousands of weekly orders of Schedule II controlled substances and Schedule III narcotics that exceeded Walmart's own established thresholds without documenting facts about those

shipments necessary to determine if those orders or future orders from the same pharmacies were suspicious.

633. Because Walmart did not maintain these records, Walmart compliance personnel charged with scrutinizing and determining whether an order from one of its more than 5,000 pharmacies was suspicious lacked the necessary facts to complete their important gatekeeping role with respect to other orders.

2. From August 2015 through November 2017, Walmart adopted a modified system for detecting and reporting suspicious orders, but this system remained defective.

634. As explained above, Walmart recognized the extensive flaws with its SOM program and the limitations of the Reddwerks and KNAPP systems.

635. Walmart attempted to address the flaws with a few modifications to its existing Reddwerks system.

636. Walmart hired a consulting firm, Mu Sigma, to review a statistical methodology for identifying suspicious orders that Walmart had designed on its own. Walmart's proposed statistical methodology would implement pharmacy-specific and drug-specific thresholds to replace the 20-bottle and 50-bottle thresholds that Walmart had been using in Reddwerks.

637. Mu Sigma reviewed Walmart's proposed revisions to its system and identified several flaws with the proposed statistical methodology. According to a January 2014 Mu Sigma report to Walmart, the "shortcomings" in Walmart's proposed approach included an inability to detect patterns over time and one-size-fits-all minimum thresholds.

638. Mu Sigma proposed a more effective methodology that would capture outlier orders missed by Walmart's proposed approach.

639. Walmart rejected Mu Sigma's proposed approach in part due to cost. In March 2014, K.S., a Senior Manager for Logistics, expressed, "[Mu Sigma] quoted us $185,000 for the

work which, I think, is ridiculous."

640. That year, Walmart reported operating profit of approximately $27 billion.

641. In or about August 2015, Walmart implemented the statistical methodology that Mu Sigma had informed Walmart was flawed.

642. Walmart continued to use this modified system from approximately August 2015 through November 29, 2017.

a. Despite the modifications to Reddwerks, many of the same flaws remained.

643. Walmart's modifications to Reddwerks failed to fix many of the serious defects from its prior SOM program.

644. Walmart's modified SOM program still failed to detect whether orders were of an unusual frequency or unusual pattern, much less report those kinds of unusual orders.

645. Walmart's modified SOM program continued to ignore known incidents of diversion occurring at its pharmacies.

646. Walmart's modified SOM program still did not consider whether a pharmacy was ordering the same controlled substance of the same drug strength, but with multiple NDCs. As noted above, this system defect permitted pharmacies to place orders well beyond the size thresholds without those orders ever being flagged.

647. In addition, Walmart's modified SOM program, when determining whether an order placed with a Walmart distribution center was suspicious, continued to ignore at least hundreds of thousands of orders that its pharmacies placed with independent distributors.

648. Walmart still had no visibility into orders that Sam's Club-branded pharmacies placed directly with AmerisourceBergen. For example, in November 2015, a pharmacist at a Sam's Club-branded store requested a threshold increase directly from AmerisourceBergen,

bypassing Walmart's compliance unit. In a December 2015 email, M.J., a Director of Controlled Substances, recognized that threshold-increase requests made by Sam's Club-branded pharmacies directly to AmerisourceBergen limited Walmart's "visibility into Sam's from a SOM standpoint."

649. Even as late as May 2017, Walmart had the same lack of visibility into orders that Walmart-branded pharmacies placed directly with McKesson. In a May 3, 2017 email, M.J. discussed the rollout of a new project that would "reduce the number of orders going directly to McKesson from the pharmacy. Those direct to McKesson orders limit our ability to get full visibility to what pharmacies order and this project will be very helpful to us."

650. As a consequence of these continuing problems with its SOM system, Walmart failed to report at least hundreds of thousands of suspicious orders to DEA, in violation of the law.

b. Walmart continued to fail to report unusually large orders.

i. Walmart's use of average order sizes to set thresholds in the midst of the ongoing prescription drug abuse epidemic failed to detect unusually large orders.

651. In mid-2015, Walmart changed the Reddwerks thresholds that it used to detect unusually large orders placed by its pharmacies.

652. Walmart modified its prior approach of applying uniform numeric thresholds to its pharmacies' orders (*i.e.*, the 20-bottle threshold for Schedule II drugs and the 50-bottle threshold for Schedule III, IV, and V drugs). Instead, it imposed pharmacy-specific, drug-specific, weekly thresholds.

653. To set these new thresholds, however, Walmart chose a flawed approach that would detect suspicious orders only in the rarest of instances. For pharmacies that typically ordered large quantities, Walmart flagged all orders that were more than three standard

deviations from that pharmacy's average order size for that drug. For pharmacies that typically ordered smaller quantities, Walmart flagged all orders that were more than three standard deviations from the average order size of all of Walmart pharmacies' orders for that drug.

654. Walmart adopted this approach despite knowing that it was likely to cause Walmart not to detect many orders that were outliers. In early 2014, Mu Sigma, the consulting firm working with Walmart to validate its proposed new methodology, had warned Walmart that Walmart's approach might not detect some unusually large orders.

655. Also, in setting pharmacy-specific thresholds, Walmart chose baselines that were flawed. Walmart used pharmacy averages based on orders from a 52-week period during a time when, as Walmart was well aware, the prescription drug abuse epidemic was raging across the country.

656. Had Walmart lawfully rejected and reported suspicious orders before it modified the Reddwerks system, then these order averages would have been lower. But by relying on already excessive orders to calculate a pharmacy's average order, Walmart created an inflated average that masked the suspicious nature of those—and subsequent—orders.

657. Walmart's decision to set thresholds for pharmacies based on inflated pharmacy averages caused Walmart to fail to report suspicious orders.

ii. Walmart's minimum threshold was too high to detect orders that were unusually large for some pharmacies.

658. As described above, the modified Reddwerks system set pharmacy-specific, drug-specific order-size thresholds based on pharmacy averages.

659. The lowest possible threshold for any controlled substance was 2,000 dosage units per week. Walmart had simply decided that the minimum threshold for flagging an order—no matter which pharmacy had placed the order and how small that pharmacy's average order plus

three standard deviations was—would be 2,000 dosage units per week.

660. For many of Walmart's pharmacies, the 2,000-unit minimum threshold for triggering suspicious-order monitoring was far too high to enable Walmart to detect whether an order was unusually large.

661. Some pharmacies, for instance, typically ordered far below 2,000 dosage units of particular drugs in any given week. This minimum threshold meant that those pharmacies could place an order for an unusually large quantity *for that pharmacy* without that order ever being flagged.

662. The inadequacy of the 2,000-unit minimum threshold for detecting unusually large orders is illustrated by considering a hypothetical Walmart pharmacy's orders. For example, suppose that over the course of a year, a Walmart pharmacy had received an average of 350 units of oxycodone-acetaminophen 5/325mg per week, and its average plus three standard deviations was 1,100 units of oxycodone-acetaminophen 5/325mg. In that scenario, under the modified SOM system, Walmart would have significantly raised that pharmacy's threshold from 1,100 dosage units to the minimum threshold of 2,000 dosage units. Accordingly, that pharmacy could have placed an unusually large order of oxycodone-acetaminophen 5/325mg—more than five times its average amount of this powerful opioid—without that order being flagged as an unusual size for that pharmacy.

663. As a result of the 2,000-unit minimum threshold, Walmart failed to detect aberrant order sizes for those pharmacies that typically ordered smaller amounts of drugs and, therefore, failed to report many suspicious orders to DEA.

iii. Walmart continued to fail to report to DEA unusually large orders by cutting those orders.

664. From August 2015 through November 2017, Walmart continued to manipulate its

SOM program in a manner that avoided reporting unusually large-sized orders to DEA.

665. During this period, for some orders that exceeded size thresholds, Walmart continued to "cut," *i.e.*, reduce the size of, those orders, without reporting the initial order to DEA, and then shipped the reduced order.

666. Walmart engaged in cutting orders on a routine basis. For example, over the course of four separate weeks in the fall of 2015, Walmart cut and shipped more than 50 orders without ever reporting these orders to DEA.

667. Upon information and belief, Walmart continued to cut unusually large orders without reporting them to DEA, through at least November 29, 2017.

668. Sometimes, Walmart did not simply reduce an unusually large order, but rejected the order altogether without filing a suspicious-order report with DEA. Over the course of four separate weeks in the fall of 2015, Walmart rejected more than 30 orders by cutting those orders down to zero bottles. Walmart did not file a suspicious-order report for any of these rejected orders.

669. Upon information and belief, Walmart continued to cut certain unusually large orders to zero bottles through at least November 29, 2017.

670. Sometimes, Walmart recorded in Archer that it was not filling the original order, but instead cut the order down to the maximum threshold amount, without further explanation. In other words, Walmart's response to an unusually large order was to ship the pharmacy the largest amount it could ship that was consistent with the threshold—without any apparent investigation of the unusually large order and without reporting the order to DEA.

671. For instance, on September 24, 2015, Store 3633 in Waynesboro, Pennsylvania, placed an order for 12 bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's

SOM system and went to the Home Office for evaluation. Home Office personnel called the pharmacy at Store 3633, which in turn related that the pharmacy "just wanted to receive the weekly threshold." On September 24, 2015, Walmart's Home Office "cut" the order down to 11 bottles. Walmart never reported the initial suspicious order of 12 bottles to DEA. The "reason code" for the cut order in Reddwerks was listed simply as "Error-System(POS)."

672. The next day, on September 25, 2015, Store 3633 placed an additional order for two bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's SOM system and went to the Home Office for evaluation. Walmart's Home Office "cut" the order down to zero bottles. Walmart never reported the suspicious order of two bottles to DEA. The "reason code" for the cut order in Reddwerks was listed as "Error-System(POS)."

673. The same day, Walmart took the same approach with an order from a different pharmacy. On September 25, 2015, Store 2281 in West Mifflin, Pennsylvania, placed an order for nine bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's SOM system and went to the Home Office for evaluation. Home Office personnel called the pharmacy at Store 2281, which in turn related that the pharmacy "would only like to receive the weekly threshold amount." On September 25, 2015, Walmart's Home Office "cut" the order down to four bottles. Walmart never reported the suspicious order of nine bottles to DEA. The "reason code" for the cut order in Reddwerks was listed as "Error-System(POS)."

674. At other times, Walmart would record in Archer that the original order was a "mistake" or "error," without any explanation of the nature of the alleged mistake or error.

c. Walmart set hard limits for pharmacies that had already placed suspicious orders—then disregarded those hard limits.

675. Another problem with Walmart's SOM system during this time period was that Walmart allowed its pharmacies to exceed hard limits that it had imposed on certain controlled

substances following the submission of a suspicious-order report to DEA.

676. In those rare instances when Walmart filed a suspicious-order report with DEA for an unusual order placed by a pharmacy, Walmart would sometimes put the pharmacy on a "remediation plan." When a Walmart pharmacy was placed on a remediation plan, Walmart would often reduce the quantity of the particular drug and strength that had been the subject of the suspicious-order report. Walmart accomplished this reduction by assigning the pharmacy a weekly hard limit for that drug. The duration of the remediation plan was usually one to two months.

677. Walmart distribution centers often blatantly disregarded the weekly hard limit set in remediation plans.

678. For example, Walmart placed Store 2530 in Rutland, Vermont, on a two-month remediation plan following the March 2, 2017 placement of a suspicious order of 23 bottles of buprenorphine HCL 8mg, an order that brought that pharmacy's weekly total to 65 bottles. The remediation plan limited Store 2530 to a weekly hard limit of 50 bottles for this drug through May 5, 2017. However, during two separate weeks over the course of the remediation period, Walmart shipped 71 bottles and 67 bottles, respectively, to Store 2530 without reporting these orders to DEA.

679. Store 2530 exceeded its remediation-plan hard limit for two additional weeks when it was on the remediation plan by placing buprenorphine HCL 8mg orders fulfilled by both McKesson and Walmart. Over a one-week period in April 2017, Walmart shipped 50 bottles of buprenorphine HCL 8mg to Store 2530, and McKesson shipped two bottles, for a total of 52 bottles, exceeding the remediation plan hard limit by two bottles. During the last week of Store 2530's remediation plan in May 2017, Walmart shipped 50 bottles of buprenorphine HCL 8mg

to the pharmacy, and McKesson shipped 106 bottles. The total of 156 bottles in that one week was more than three times Store 2530's remediation-plan hard limit of 50 bottles.

680. In another example, following an August 23, 2017 suspicious order of 42 bottles of hydrocodone-acetaminophen 10/325mg for a total weekly order of 79 bottles, Walmart placed Store 130 in Muskogee, Oklahoma, on a remediation plan for hydrocodone-acetaminophen 10/325mg. The remediation plan limited Store 130 to a weekly hard limit of 50 bottles of hydrocodone-acetaminophen 10/325mg from August 25, 2017, through October 20, 2017. Yet during at least during one week of the remediation plan, Walmart shipped 61 bottles to the pharmacy, ignoring the 50-bottle weekly limit without reporting this order to DEA.

C. Walmart's flawed approach to monitoring pharmacy orders resulted in a failure to detect and report at least hundreds of thousands of suspicious orders.

681. All of the significant shortcomings from the initial Reddwerks system and the modified Reddwerks system rendered Walmart's SOM program ineffective and, as a result, Walmart failed to detect and report suspicious orders to DEA, as required by law.

682. The United States estimates that from June 26, 2013, through November 29, 2017, Walmart shipped approximately 15.2 million orders of Schedule II controlled substances and Schedule III narcotics to its own pharmacies. This figure does not include any other Schedule III controlled substances, or any Schedule IV and Schedule V controlled substances. The United States estimates that from June 26, 2013, through November 29, 2017, Walmart shipped approximately 37.5 million Schedule II, III, IV and V orders to its pharmacies.

683. During the same time period, Walmart reported only 204 suspicious orders to DEA—an infinitesimal percentage.

684. Walmart's ultralow rate of suspicious-order reporting is incredible. The small number of suspicious orders Walmart reported cannot be credibly attributed to a lack of unusual

or otherwise suspicious orders placed by its pharmacies.

685. By comparison, McKesson, the independent distributor that served as the back-up distributor to Walmart-branded pharmacies, received far fewer orders from Walmart's pharmacies but reported to DEA more than 13,000 suspicious orders from Walmart pharmacies between June 26, 2013, and November 29, 2017.

686. Walmart's failure to report suspicious orders stems from Walmart's decisions to operate a system that failed to detect suspicious orders and to manipulate that system to avoid reporting to DEA those suspicious orders that were detected.

D. Walmart's failure to detect and report suspicious orders deprived Walmart of the opportunity, during the prescription drug abuse epidemic, to timely address potentially unlawful conduct.

687. Walmart's failure to detect and report suspicious orders not only violated the law, but also inhibited Walmart's ability to timely investigate the suspicious orders and uncover potentially unlawful conduct.

688. Before reporting suspicious orders to DEA, Walmart first had to identify the suspicious orders for itself. The regulation explains that the distributor must design and operate a system "to disclose *to the registrant* suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b) (emphasis added).

689. If Walmart had properly identified suspicious orders in the first place, as required by the regulation, steps could have been taken to investigate the orders.

690. For example, under a policy Walmart adopted in 2015, once it identified a suspicious order, it would develop a "remediation plan" for the pharmacy that placed the suspicious order. Under this policy, Walmart would conduct an investigation into the reasons for the unusual order. This investigation could include engaging Walmart's Global Investigations group to open a review of the ordering pharmacy and requiring an on-site visit by Health and

Wellness Operations to conduct a review and additional training at the pharmacy. The policy required Walmart to "document the final conclusion of the evaluation" and "retain documentation of any reports made to the DEA and state agencies." Also, under the policy, Walmart could increase oversight of future orders from the pharmacy.

691. If Walmart had complied with its obligation to detect and report suspicious orders, it would have investigated the reasons for those orders and initiated remediation plans. It thus could have taken steps that might have led to the timely detection of unlawful, improper, or dangerous conduct. For example, Walmart could have discovered that the unusually high demand for a controlled substance at a particular pharmacy was resulting from dispensing at that pharmacy for a "pill mill" prescriber.

692. For the at least hundreds of thousands of suspicious orders that Walmart never even identified, Walmart did not institute remediation plans to inquire into the orders, and it never informed DEA of those suspicious orders.

693. When Walmart fulfilled suspicious orders, Walmart's approach allowed dangerous controlled substances to enter the market. Even in those circumstances where Walmart recognized that certain orders were "suspicious" after those orders had already been shipped to its stores, Walmart's failure to report those orders and take other remedial steps allowed the ordered drugs to "enter the market." As a Senior Manager for Logistics wrote in an August 20, 2014 email, "[t]he alternative to pulling the order back is to simply continue to follow the process we have today. We can add further evaluation of orders after shipment but, if we see an issue that suggests that product shouldn't have been shipped, we just leave it at the store and let it enter the market. Given the choices, [having the store] ship… the product back feels like the more socially responsible approach, but the [Distribution Center] will do whatever leadership

wants them to do."

694. Walmart's systematic failure, for years, to comply with its legal obligation to detect and report each of its suspicious orders thus created a major obstacle to efforts to combat the prescription drug abuse epidemic.

695. Walmart also financially benefited from these violations of law. Walmart chose to avoid the expense of creating and implementing a proper program for monitoring and reporting suspicious orders. For example, Walmart avoided the expense of creating and implementing a remediation plan for each suspicious order, which could have imposed burdens on Walmart and might also have uncovered improper activity that Walmart would have to remediate. Likewise, Walmart avoided the expense of paying for adequate numbers of compliance personnel. Most critically, Walmart profited by providing its pharmacies with unusually large quantities of controlled substances to sell, and from selling other products to customers who came to Walmart stores only because Walmart pharmacies would readily provide these controlled substances.

696. In sum, Walmart chose, for years, to disregard a well-established legal obligation on a systematic basis and a huge scale involving at least hundreds of thousands of orders of controlled substances. In doing so, Walmart substantially benefited itself while increasing the risk of undetected unlawful conduct and serious widespread harm to Americans in the midst of a nationwide prescription drug abuse epidemic.

CLAIMS FOR RELIEF

FIRST CLAIM
(For civil penalties and other relief, based on violations of 21 U.S.C. §§ 842(a)(1) & 829 and 21 C.F.R. § 1306.04(a))

697. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

698. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.04(a), because it, through its agents and employees, knowingly dispensed controlled substances pursuant to prescriptions that were either not issued in the usual course of professional treatment, not for a legitimate medical purpose, or both.

699. Walmart violated these provisions on multiple occasions, with the precise number of violations to be established at trial.

700. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

701. The United States also requests that the Court issue an order granting appropriate injunctive relief tailored to restrain Walmart's violations of 21 U.S.C. § 842. *See* 21 U.S.C. § 843(f).

SECOND CLAIM
(For civil penalties and other relief, based on violations of 21 U.S.C. §§ 842(a)(1) & 829 and 21 C.F.R. § 1306.06)

702. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

703. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.06, because

it, through its agents and employees, did not adhere to the usual course of the professional practice of pharmacy in filling prescriptions for controlled substances.

704. Walmart violated these provisions on multiple occasions, with the precise number of violations to be established at trial.

705. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

706. The United States also requests that the Court issue an order granting appropriate injunctive relief tailored to restrain Walmart's violations of 21 U.S.C. § 842. *See* 21 U.S.C. § 843(f).

THIRD CLAIM
(For civil penalties, based on violations of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b))

707. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

708. During the Distribution Violations Period, from June 26, 2013, through November 29, 2017, Walmart refused or negligently failed to report suspicious orders to DEA, in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b).

709. Walmart violated 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b) on multiple occasions, with the precise number of violations to be established at trial.

710. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(B).

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests judgment to be entered in its favor and against Walmart as follows:

a. Awarding a sum equal to civil penalties to the maximum amount allowed by law;

b. Granting injunctive relief to address and restrain Walmart's violations of law; and

c. Granting the United States such further relief as the Court may deem proper.

Respectfully submitted,

Dated: December 22, 2020

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